

# Research into Spinal Deformities 9



Editors: Xue-Cheng Liu  
John G. Thometz

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It is over 70 years since two orthopedic surgeons invented the Milwaukee brace for the treatment of children with scoliosis. Since then, clinicians and researchers have been inspired to design ever more effective braces to correct 3-D spinal deformities.

This book presents papers from the bi-annual meeting of the International Research Society of Spinal Deformities (IRSSD), held as a virtual event on 22 and 23 January 2021. The IRSSD concentrates on research into spinal deformity with clinical applications. In addition to 3D assessment of the spine, researchers also explore spinal biomechanics, etiopathogenesis, and innovative conservative and surgical therapies with the goal of integrating science with clinical care to improve patient care. The 2021 meeting was originally scheduled to take place in Milwaukee, Wisconsin, USA, but was instead held in a virtual format due to the Covid 19 pandemic. Despite this change, the meeting still allowed valuable interaction and open discussion among practitioners from around the world, and keynote speakers and authors contributed the 44 short papers and 47 abstracts included here. The papers are grouped under 17 chapter headings, and cover a wide range of topics, including biologic and biomechanical benchmarks, clinical evaluation, conservative treatments and surgical approaches. Diagnostic assessments and non-surgical treatments of EOS are also emphasized and elucidated.

The book will be of interest to all those whose work is related to the treatment and care of patients with spinal deformities.



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*This book is dedicated to the memory of Dr. Walter Blount and Dr. Alfred C. Schmidt who created the Milwaukee brace.*

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# Foreword

In January 2021 the International Research Society of Spinal Deformities (IRSSD) held its bi-annual meeting in Milwaukee, Wisconsin, USA. Originally the meeting was scheduled in Milwaukee at an iconic Milwaukee hotel, the Pfister, but the pandemic intervened and necessitated the transition of the meeting to a virtual format. Even so, the meeting allowed interaction and open discussion amongst practitioners from around the world.

The IRSSD is an outgrowth of a group of researchers who met in 1980 to discuss surface topography and other techniques for assessment of trunk deformity. The society has always been multi-disciplinary in nature, and over the years there was seen to be a need to broaden the scope of the meeting, which led to the formation of the IRSSD.

Initially the groups emphasis was on surface topography but the society now studies a variety of methods to assess the 3D deformity of scoliosis, including EOS 3D reconstruction.

The IRSSD concentrates on research in spinal deformity with clinical applications. In addition to 3D assessment of the spine, researchers also explore spinal biomechanics, etiopathogenesis, and innovative conservative and surgical therapies. The goal is to integrate basic science with clinical care to improve patient care.

The first IRSSD meeting was held in 1996 in Sweden, hosted by John Sevastick. The second meeting was held in 1998 in Vermont and was hosted by Ian Stokes. The third meeting was held in 2000 in Clermont Ferrand, France, hosted by Alain Tanguy and Bernard Peuchot. The fourth in 2002 in Athens, Greece, organized by Dr. Theodoros B. Grivas.

Since then, the society has met in multiple countries around the world.

For the meeting we were lucky to have four keynote speakers of international note...

*Patrick Cahill, MD; The Children's Hospital of Philadelphia*

Pulmonary Outcomes in Pediatric Spinal Deformity Surgery

*Stefan Parent, MD, PhD; Sainte-Justine Hospital*

Optimizing Surgical Results of Vertebral Body Tethering

*Brandon Rebholz, MD; Froedtert & the Medical College of Wisconsin*

Adaptation of Emerging Technologies in Adult Spinal Deformity Surgery

*Carol Wise, PhD; Texas Scottish Rite Hospital for Children*

What Causes AIS? Ask the Genome!

We also hosted 4 symposia on current controversies with experts in the field...

Eliminating 2D Spinal Assessments and Embracing 3D and 4D

*Patrick Knott, PhD, PA-C, Xue-Cheng Liu, MD, PhD, and Saba Pasha, PhD*

Gait and Posture Analysis in Scoliosis-Implications for Clinical Practice

*Nachi Chockalingham, PhD, Ram Haddas, PhD, Robert Needham, PhD, and Thomas Shannon, PhD*

Future Generation of Brace

*Carl-Eric Aubin, PhD, PE, Man-Sang Wong, PhD, and Luke Stikeleather, CO*

Bracing for the Early Onset Scoliosis

*Timothy Hresko, MD, Channing Tassone, MD, John Thometz, MD, and Jim Wynne, CO*

We are grateful to have had the opportunity to host this meeting. I would especially like to thank my co-chairman, Dr. Xue-Cheng Liu. His excellent skills in both the clinical and basic science research arena, along with his tireless efforts and outstanding productivity, made this meeting a success. The book is meant to further the mission of the IRSSD in expanding the scope of scoliosis research.

John Thometz  
Milwaukee, Wisconsin  
USA  
March 16, 2021

# Preface

Over seven decades ago, two orthopedic surgeons from our institution invented the well-known Milwaukee brace for the treatment of children with scoliosis. Since then, it has inspired clinicians and researchers to design more effective braces to correct 3-D spinal deformities. Two symposiums introduced a customized brace for the Early Onset Scoliosis (EOS) and a next generation brace in Adolescent Idiopathic Scoliosis (AIS). Because of this, we became more acquainted with the CAD/CAM based brace as an alternative to serial casting for EOS, and a numerical simulation model to improve the design of future braces. Since its inception in 1994, our society pioneered the development of surface topographic systems and various clinical applications in the 3-D assessment of trunk asymmetry. Then, the third symposium provided a deeper understanding of the dynamic evaluation of trunk metrics by incorporating 3-D and 4-D spinal measurements. These metrics are calculated by using surface topography, ultrasound, and a 3-D spinal classification system based on reconstruction of biplanar radiographs. The fourth symposium shed light on kinematic and kinetic analyses in children with AIS, both in the academic and community-based settings.

This book (Series 9) has been strengthened by keynote speakers and authors who contributed 44 short papers and 47 abstracts at the 2021 International Research Society of Spinal Deformities Congress (IRSSD). The traditional chapters cover a broad range of topics, including biologic and biomechanical benchmarks (genetics, etiology, growth, metabolism, posture and movement, and pressure), clinical evaluation (3-D surface topography, 3-D biplanar radiographic reconstruction, MRI, Ultrasound, and functional outcomes), conservative treatments (casting, bracing, and physiotherapy), and surgical approaches (growth modulation device, and hybrid hook and pedicle screw etc.). Additionally, we have emphasized and elucidated the diagnostic assessments and non-surgical treatments of EOS.

Apart from the excellent authors, it would be impossible to feature this book without the supportive staffs and sponsors mentioned in the acknowledgement section. I would like to especially express my sincere gratitude and appreciation to Dr. John Thometz, a co-editor for this book. His vision, tireless dedication, and 36 years of clinical experience paved the path for this successful conference. We hope this book will integrate scientific researchers, engineers, and clinicians to address the challenges of studying and treating spinal deformities in the years to come.

Xue-Cheng Liu  
Milwaukee, Wisconsin,  
USA  
March 5th, 2021

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# Acknowledgements

The 2021 International Research Society of Spinal Deformities (IRSSD) Virtual Congress and this publication received generous support from several organizations committed to the advancement of research in the orthopaedic and rehabilitation field. Their support contributed to attendees receiving this book complimentary, honorariums for speakers and award prizes to top podium and poster abstract authors. Their generous support provided the opportunity to use a highly sophisticated virtual event platform to deliver the best possible virtual congress.

First and foremost, we would like to thank all the keynote speakers and symposium speakers: Dr. Carol Wise, Dr. Stephan Parent, Dr. Brandon Rebholz, Dr. Patrick Cahill, Dr. Patrick Knott, Dr. Saba Pasha, Dr. Xue-Cheng Liu, Dr. Nachi Chockalingham, Dr. Ram Haddas, Dr. Robert Needham, Dr. Thomas Shannon, Dr. Carl-Eric Aubin, Dr. Man Sang Wong, Mr. Luke Stikeleather, Dr. Timothy Hresko, Dr. Channing Tassone, Dr. John Thometz, and Mr. Jim Wynne. We wish to extend our thanks to all participants as well as the congress moderators: Dr. Tomasz Kotwicki, Dr. Channing Tassone, Dr. Patrick Knott, Dr. Nachi Chockalingham, Dr. Benjamin Escott, Dr. Carl-Eric Aubin, and Dr. John Thometz. Through their collective efforts, they made 2021 IRSSD Congress successful.

We also would like to express our deep acknowledgement and gratitude to the Children's Wisconsin Foundation and the following individuals who made this congress possible. They quickly adapted when the decision was made to transition the meeting from in-person to virtual, with the goal of keeping everyone's health and safety a top priority.

To the Children's Wisconsin marketing and web teams: Elizabeth Malten, Nancy Vanselow, Pam Spankowski, Chelsea Osoling, Christa Armeli, Lisa Magurany and Nancy Pontius; we appreciate the time, dedication and effort that went into the intricate planning of this meeting. Their commitment to executing the many details to ensure the success of the meeting was highly valued. Also, we want to extend great thanks to Elizabeth Malten for her continued support in processing of the book.

To the Children's Wisconsin audio visual team: Jeff Howard, Justin Whiteman and David Watson; thank you for your expertise in recording high quality presentations of the speakers, compiling the files and collaborating with the marketing and web teams during the planning timeframe.

To the Medical College of Wisconsin: we greatly appreciated research staff and administrative assistants, Ford Ellis, Myra Davis, and Claire Blanchard, for the hours spent formatting the papers for this publication, documenting the abstract submissions, and compiling the list of correspondents. We also thank the department of orthopaedic surgery for administrative support, especially Michelle Behling and Debra Soik for managing the agreement.

Last but not least, we want to convey our gratitude to the scientific committee members and award nomination committee members who reviewed the abstracts and determined the top presenters.

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# In Memoriam: Geoffrey Burwell

PH DANGERFIELD<sup>1</sup> and A MOULTON<sup>2</sup>

<sup>1</sup>*University of Liverpool and Staffordshire University,* <sup>2</sup>*Department of Orthopaedic Surgery, King's Mill Hospital, Mansfield, UK*

There is little doubt that Geoffrey Burwell was one of the most renowned academics in Orthopaedics of his generation in the UK and world. He was an Internationally recognised authority in spinal deformity and in bone grafting. Geoffrey was well known to members of the Surface Topography Group and the International Research Society for Spinal Deformities (IRSSD) for his significant contributions to the field of scoliosis, with many papers and concepts developed over many years.

Geoffrey was brought up in Leeds in Yorkshire and, in 1946, was awarded a Scholarship to study Medicine at the University of Leeds. During his time at Leeds Medical School, he won an academic prize every single year, including a 1st Class Honors for his BSc. A distinction for his Doctor of Medicine (MD) degree, on the blood supply to the kidney followed graduation.

His post graduate career commenced with House Officer posts in Leeds and London (at the Hammersmith Hospital), National Service, spent at Catterick and Gibraltar during 1955 to 1957 and then General surgical and Orthopaedic training in Leeds (1957 to 1965) and Oswestry (1965-1968). Many UK trainees spent time at Oswestry, an orthopaedic hospital dedicated to a range of condition that included scoliosis.

Unusual for those in British PG training, his career took him directly into academic medicine with his appointment in 1968 as Professor of Orthopaedics at the Royal National Orthopaedic Hospital. While there, he continued research already underway into bone grafting, and rapidly became recognised as an authority in the field. Dissatisfaction with his London position led to his resignation in 1972 and a move to Nottingham, where Professor Rex Coupland was the Professor of Human Morphology and Dean of the Medical School and was a long-time friend. He was appointed as a research fellow on a two-year contract in the Department of Human Morphology. He gained a substantial grant from Action Research for the Crippled Child (now Action Research) with Alan Moulton into scoliosis. Action Research also supported a study of ultrasound related to rotation in the lower limbs and traumatic posterior dislocation of the hip, again with Alan Moulton. His outstanding research output led to a personal Chair as Professor of Human Morphology and Experimental Orthopaedics at the University of Nottingham and an Honorary Consultant in Orthopaedics, associated with the Spinal Unit in the newly opened Queens Medical Centre on Nottingham. He supervised many MDs and undergraduate degree students, whom he encouraged to travel and present work. An example of this included the Pescara meeting of IRSSD.

During the early years of working in Nottingham, he contacted Peter Dangerfield in Liverpool who was working under Professor Robert Roaf, another important figure in the history of scoliosis. This led to years of collaboration, continuing right up to this year. Geoffrey had a breadth of interest in scoliosis, considering a range of concept relating to growth and development and analysis of the shape and form of adolescents with idiopathic curves. With Peter Dangerfield, the development of on-line discussion groups

led to publication of a series of papers on Scoliosis as well as contributing to further understanding of aetiology and pathogenesis of the condition. Geoffrey and Peter were both frequent attendees at the biennial Surface Topography group meetings and it was their work, with Dirk Uttendaele and others, that led to the successful formation of the IRSSD, which has continued to hold biannual research meetings throughout the world.

Encouraged by Professor Rex Coupland, Geoffrey became involved with the British Association of Clinical Anatomists from its inception and, with his team of researchers, was a frequent contributor to its twice-yearly scientific meetings, with presentations and posters which always attracted considerable interest from attendees. Geoffrey held a number of Honorary Appointments including in 1983 President of the British Orthopaedic Research Society and 1989 President of the British Scoliosis Society.

Reaching the age 65, Geoffrey was clearly not ready for retirement, needless to say! He continued his research at Nottingham University Hospitals with an honorary appointment, continuing for a further 22 years! Aged 87, he had to admit that...*"I haven't got enough time left to embark on a new research project"*.

Geoffrey married Helen on 19th January 1963 and for 53 years they mutually supported each other and enjoyed a long and happy marriage. They had two children, Matthew, who is an orthopaedic surgeon and Jane who works in London. Sadly, Helen pre-deceased Geoffrey but in true spirit, he continued to live for his research ideas.

His passing at the age of 89 after a rich and varied life which generated a considerable number of scientific papers marks Geoffrey as a significant contributor to research in paediatric orthopaedics as well as bone grafting. He will be sadly missed by his colleagues, friends, and ex-research students, to whom he was a great mentor and supporter.



Geoffrey Burwell at the IRRSD meeting Poznan 2012



Geoffrey Burwell, Alan Moulton and Peter Dangerfield, from left to right, respectively

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# Chapter 1

## Genetics and Etiology

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# What causes AIS? Ask the genome!

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**Abstract:** The most common developmental disorder of the spine is scoliosis, a rotated, lateral deformity in the shape of the spinal column. Scoliosis may be part of the clinical spectrum that is observed in many developmental disorders, but typically presents as an isolated symptom in otherwise healthy adolescent children. Adolescent idiopathic scoliosis (AIS) has defied pathogenic understanding in part due to its genetic complexity, and to the lack of well-defined animal models. The disease is also remarkable in its sexual dimorphism, where girls are at more than five times greater risk of progressive deformity than boys. Breakthroughs have come from recent genome wide association studies (GWAS) and next generation sequencing (NGS) of human AIS cohorts. Post-hoc gene set and pathway-level analyses of genetic datasets have highlighted a role for cartilage biogenesis and the development of the intervertebral disc (IVD) in disease susceptibility. Moreover, next generation sequencing in AIS families, as well as modeling in vertebrate systems, has revealed that rare deficiencies in proteins of the cartilaginous extracellular matrix (ECM) collectively contribute to AIS. Thus, as in a jigsaw puzzle, the pieces coming together from multiple biologic studies suggest that deficiencies in the structural integrity and homeostasis of spinal cartilages are culprits in AIS susceptibility. Here, we update progress in understanding the genetic, biochemical, and cellular determinants of AIS. We also suggest a molecular model in which interaction of the hormonal environment with genetic susceptibility may increase risk of this common disorder of childhood.

**Keywords:** Scoliosis, adolescent, genetics, cartilage, intervertebral disc

## Introduction – Why do we study AIS?

For centuries, physicians have speculated on the causes of scoliosis.[1] It is now clear that, while scoliosis can be part of the clinical spectrum of various developmental disorders, the great majority occurs in otherwise healthy children. In fact, idiopathic forms of scoliosis (IS) are the most frequent spinal disorder of childhood, occurring in ~3% of school age children, >29 million children worldwide.[2] Untreated, progressive IS is associated with restrictive lung disease, pain, and severe deformity later in life (Figure 1).[3] Curiously, the onset of IS usually coincides with the adolescent growth spurt. A child with adolescent idiopathic scoliosis (AIS) whose scoliosis continues to worsen before the peak of growth velocity is at greatest risk of serious deformity, but after skeletal maturity the risk of “curve progression” decreases sharply.[4] Another curious feature of AIS is its striking sexual dimorphism, with girls having a more than five-fold greater risk than boys of progressive deformity requiring treatment.[5]

Orthotics, may be a first-line treatment to help control progression until skeletal maturity.[6,7] Bracing is considered to have failed if the curve continues to progress significantly before closure of the growth plates.[8] For progressive AIS, the standard of care is surgery to reduce the deformity, fusing the involved vertebral bodies to prevent continued progression, and achieving balance of the head, shoulders, and trunk over the pelvis.[9] The costs of surgical correction for AIS surpass a billion USD annually just in the United States, but this cost is arguably outweighed by the physical, emotional, and financial toll on patients and families together with the inherent risks of surgery.[10] These issues have motivated intense basic research in the last few decades to address fundamental questions about AIS whose answers will drive new therapies and preventions. In particular, what biochemically drives AIS, where in the spine does it originate and when, and why is it so often progressive in females?



Figure 1. AIS in a female patient. Forward bending reveals a rib hump due to the twisting of the spine. Standing radiographs represents the three-dimensional deformity as a typical right-sided curve.

## Genetic Discoveries

Genetic epidemiologic studies have demonstrated significant but complex heritability in AIS.[11-13] In this scenario, the risk of AIS in any single patient is likely the cumulative effect of several to many genetic risk factors. Modern genomic approaches including genome-wide association studies (GWAS) and next-generation sequencing in large patient cohorts are beginning to elucidate the genetic changes underlying AIS risk.[14-23] The majority of reports thus far employ GWAS, a hypothesis-free method that maps genetic variation contributing to AIS risk in the genome relative to fixed markers, usually single nucleotide polymorphisms (SNPs).[24] By definition, SNPs are common in the population and consequently can be informative in statistical tests such as logistic regression that measure frequency differences between affected cases and matched controls. Because of the many tests performed in a typical GWAS (“multiple testing”), a significance level of  $P < 5 \times 10^{-8}$  is generally required for any association to be declared significant (GWAS-level significance) (Figure 2). Beyond this discovery, replication of GWAS-significant loci is necessary to independently validate candidate SNPs and provide realistic estimates of effect size and fraction of risk

conferred across populations. The need for sufficient statistical power and validation has motivated the formation of large collaborative groups and consortia such as the International Consortium for Spinal Genetics, Development, and Disease (ICSGDD).[25] As one example, we previously performed a collaborative study that defined AIS risk variants in a putative regulator (“enhancer”) of *PAX1*, a well-described early marker of somitogenesis whose expression is later restricted to the intervertebral disc (IVD).[26-28] Further, we found that the evidence for genetic association and the calculated odds ratios for alleles at the locus increased significantly when males were removed from the analysis, despite the decrease in sample size. These data suggested that the *PAX1* enhancer locus drives AIS predominantly in females, rather than males.[29] A subsequent expanded GWAS meta-analysis of 33,476 individuals, also organized through the ICSGDD, identified significant enrichment of genetic variation in pathways involved in cartilage/connective tissue biogenesis.[23] These results brought particular focus to the regulation of IVD development and maintenance (Figure 3). Further, rare mutations in cartilage collagens have been associated with scoliosis in humans and zebrafish,[30,31] leading to the hypothesis that deficiencies in extracellular matrix proteins, the so-called “matrisome” could contribute to AIS etiology.[10]

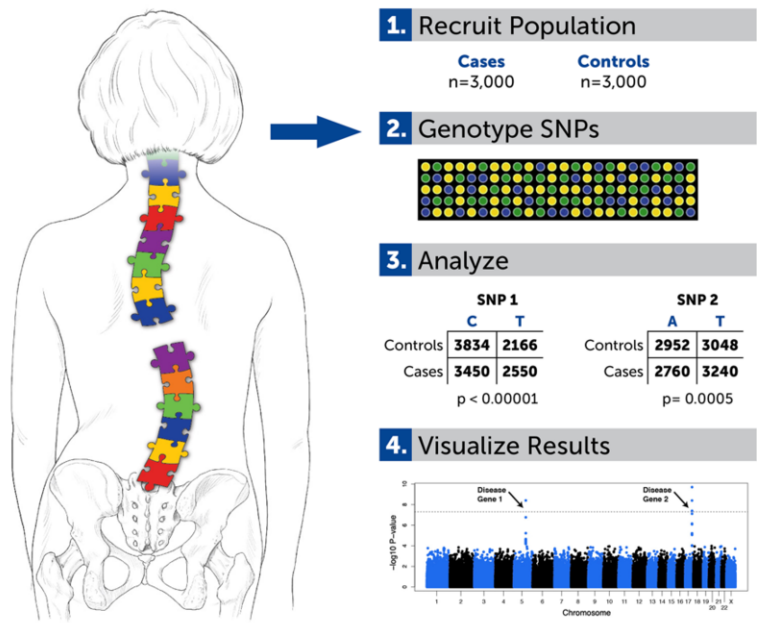


Figure 2. Population-based studies of AIS. AIS is a complex genetic disease, likely caused by many genetic risk factors interacting as pieces in a puzzle. Genome-wide association studies (GWAS) (right) in large patient cohorts are elucidating the genetic changes underlying AIS risk. In this example, microarray-based genotyping of more than 500,000 SNPs in thousands of cases and controls is followed by statistical analyses to detect differences. The results are typically visualized in plots that show every SNP in chromosome order (X-axis) versus the associated inverse log P-value (Y axis).

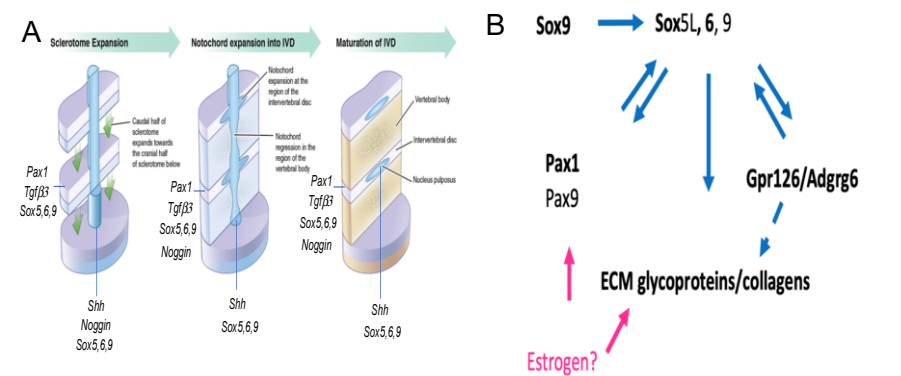


Figure 3. AIS candidate genes participate in the development of the intervertebral discs. The components of the IVD are derived from the sclerome and notochord in early spinal development. (A) Genes associated with AIS susceptibility, including *Pax1* and *Sox* transcription factors are key regulators of this process. (B) AIS-associated genes “fit together” in a pathway of chondrocyte maturation that is important in the IVD. We hypothesize that estrogen may regulate this pathway in cartilaginous cells.

A Model of AIS Pathogenesis

The three major compartments of the IVD—nucleus pulposus, annulus fibrosis, and endplates-- are essential to withstanding and dissipating the forces along the spine, including the forces of growth. In the intact disc, osmotic swelling within the NP is resisted radially by the collagen fibers of the AF and axially by the endplates and vertebrae. The AF then effectively absorbs compressive and torsional loads.[32,33] Thus, the three components of the disc are “greater than the sum of the parts”, serving to support and maintain each other as they collectively bear loading of the spine while conferring mobility. Deficiencies in any one part of the disc can impact the whole and, in the mature organ, lead to irreversible damage. The ECM is a critical functional compartment of the IVD, providing mechanical strength, regulating nutritional flow as noted, and conveying physiologic signals back to the cells.[34] Predominant components of the cartilage matrisome are fibrillar collagens, chondroitin sulfate proteoglycans, and hyaluronic acid. These large molecules form the basic structural network of the matrisome that allows other factors and cells to interact.[35,36] While the IVD appears superficially healthy in AIS, these findings raise the prospect of deficiencies at the biochemical level. Radiographic studies have suggested a role for the IVD in AIS. For instance, in AIS patients that were followed longitudinally, wedging of involved discs preceded wedging of involved vertebrae until the end of the growth spurt.[37] However, whether alterations in components of the IVD are necessary or sufficient to cause AIS is not clear at present. It is intriguing to speculate however that the IVD may contribute to differential progression in females compared to males. The female-predominant contributions of a *PAX1* enhancer hint at this. Moreover, at least one IVD collagen, COL11A1, is regulated by estrogen in other tissues.[38] Further studies of the spatio-temporal expression of specific AIS candidate genes and targeted vertebrate models will be key addressing these questions.

## Summary

Adolescent idiopathic scoliosis is a common and complex disorder caused by the effects of many genetic risk factors. The increased risk of progressive disease in girls suggests an interaction of the hormonal environment with genetic susceptibility. Emerging genomic studies point to the biochemical development and/or maintenance of the IVD in AIS susceptibility. These discoveries set up future research to create genetically targeted vertebrate models of AIS that will enable detailed understanding of disease onset and progression. Importantly, these studies also raise the prospect of future AIS treatments or preventions aimed at preserving IVD health.

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# The sagittal curvature of the spine can be a leading cause of scoliosis in pediatric spine

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**Abstract:** The etiology of the adolescent idiopathic scoliosis (AIS) remains unknown. Variations in the sagittal profile of the spine between the early stage scoliotic and non-scoliotic pediatric patients have been shown. However, no quantitative study has shown the link between the sagittal profile and 3D deformity of the spine. 126 right thoracic scoliosis with spinal and 3D reconstructions were included. A 2D finite element model was developed for each of the sagittal curve types without any deformity in the frontal or axial planes. Physiological loadings were determined from the literature and were applied in the finite element model. The 3D deformation patterns of the models were compared to the 3D spinal patterns of the AIS with the same sagittal type. A significant correlation was found between the 3D deformity of the scoliotic curves and the numerical finite element simulation of the corresponding sagittal profile as determined by pattern correlation,  $p < 0.001$ . The sagittal curve deformation patterns corresponded to the spinal deformities in the patients with the same sagittal curvature. Finite element models of the spines, representing different sagittal types in 126 AIS patients showed that deformation pattern of the sagittal types changes as a function of the spine curvature and associates with the patterns of 3D spinal deformity in AIS patients with the same sagittal curves. This finding provided evidence that the sagittal curve of the spine can determine the deformity patterns in AIS.

**Keywords:** Adolescent idiopathic scoliosis; Pathomechanism; Sagittal profile; Thoracic Curve

## Introduction

While several theories have been developed around the etiology of scoliosis, the pathomechanism of the curve development in otherwise healthy adolescents remain unknown. The sagittal curvature is shown to vary between the scoliotic and non-scoliotic patients even at an early stage of the curve development.[1,2] The mechanics of elastic rod with and S-shaped curve, representing the sagittal curvature of the human spine, showed to replicate scoliotic-like deformation patterns.[3,4] Yet, it is not shown if in a group of patients with the same curve pattern i.e. right thoracic AIS, variations in the sagittal profile is linked to the 3D subtypes.

We previously introduced the rod theory explaining how the pediatric spine, when considered as a slender flexible elastic rod, can explain the spinal deformation patterns in AIS.[5] This model for explaining the pathomechanism of scoliosis also suggests

that considering the growth in pediatric spine, forces and moment are induced along the spine that unstabilize the spine and cause scoliosis.[5,6] The mechanics of the deformable rods can show that such forces can change as a function of the geometrical parameters of the sagittal curvature making the pediatric spine prone to 3D curve development in certain sections of the spine. The latter explained the variation in the location of frontal curve in AIS patients.[5]

Growth is shown to cause instability in elastic material. Growth can make a rod to reach a critical length that makes it unstable. Other way said, there is a critical growth rate that can cause instability in a system that was stable before. Moreover, growth is accompanied by increase in mass, another factor that can impact the stability of the growing structure. Research has also shown the rate of spinal growth in AIS patients is faster than the normal population however this trend was not observed when the lower limb growth rate was compared between the age-sex match AIS and non-scoliotic adolescents. A faster growth rate while the intervertebral discs are maturing and weight increases, can cause a torsional instability, as explained by mechanics of elastic rods.[7-10]

Considering both growth and sagittal shape of the spine, we introduced a reduced ordered model of the spine to explain the pathomechanism of scoliosis. In the current study we aimed to determine whether variation in the sagittal curvature of the spine relates to the 3D deformation patterns of the spine while spine is exposed to gravitational loading as result of the trunk weight and axial torsion representing growth. This model was used to simulate various sagittal curve patterns, observed in a cohort of AIS patients, and compare the biomechanical behavior of the model to the 3D deformity of the scoliotic spine.

## **Methods**

A cohort of 126 right thoracic AIS was included retrospectively. The biplanar radiographs and the 3D reconstruction of the spine were included. The 3D model of the spine was used to calculate the 3D vertebral centroids using a previously describe method. The spinal curvature in the sagittal plane was determined by connected the vertebral centroids and interpolating the 2D location of these centroids in the sagittal plane.

The sagittal curvature was used to develop a reduced order finite element model of the spine. This model represent an S-shaped elastic rod under bending and torsion a model of the pediatric spine. The bending moment is induced as a result of the trunk weight and the axial torsion was applied to break the system symmetry and allow 3D deformation while representing the torsional instability resulting from growth [6]. The direction of this torsion was selected by the trunk mass asymmetry in average population. The 2D rods deformed in 3D as a result of such loading. This model was created for all the 126 cases of right thoracic using their sagittal curvature. The 3D deformation patterns of the rods were compared to the 3D deformation patterns of the AIS patients. This comparison was performed by identifying the shape (loop versus lemniscate) and comparing the similarity between the curves using pattern correlation analysis.



## Results and Discussion

The 2D rod models deformed in two patterns: the first pattern was a loop shaped deformation in which the axial projection of the curve did not cross itself, and the second pattern was a lemniscate shaped deformation in which the axial project of the curve formed a figure-eight type deformation and the curved crossed itself (Figure 1). The same deformation pattern was observed in the AIS patient with corresponding sagittal curves.

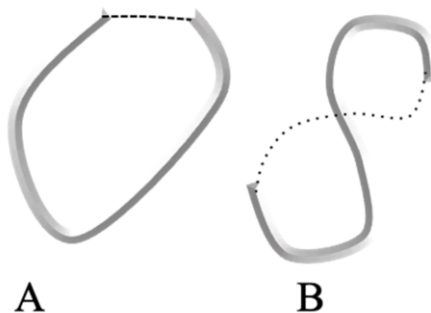


Figure 1. A) Loop and B) Lemniscate shape presentation of the axial projection of the S-shaped elastic rod.

The sagittal profile of the AIS patients with a loop-shaped axial projection consisted of a longer spinal section with a lordotic curve. On the other hand the sagittal profile of the patients with a lemniscate shape axil project the length of the spine with a kyphosis and lordotic curve was closer (Figure 2). Comparing the axial projections between the simulated deformation and patient deformation showed significant similarity between clinical and simulated data.

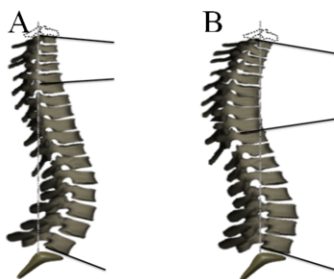


Figure 2. Schematics of the sagittal profile of the right thoracic AIS patients with A) loop and B) Lemniscate shape axial projections. Comparison between the kyphotic and lordotic sections of the spine is shown for the two sagittal types.

The hypothesis that the 3D deformation patterns of the scoliotic spine relate to the sagittal curve patterns was tested here. This hypothesis was tested in light of the theory that pediatric spine at the period of fast growth can behave similar to an elastic rod and

deform in 3D when bending and small torsional moment are imparted on the rod. The results showed that two 3D subtypes of the right thoracic AIS, one with one long 3D curve and one with two 3D curves twisted in opposite directions, have distinguishably different sagittal curves. The differences between the sagittal curves were shown the spinal lengths with kyphotic and lordotic curves.

A challenge in studying the pathogenesis of scoliosis is access to patients before the onset of curve development. As mentioned AIS patients, more often than not, are not presented with other underlying conditions, thus the medical images of the spine are only acquired after the onset of the curve development. That small deformity can impact the 3D shape of the spine and makes the patho-mechanistic analysis of the curve development challenging. To overcome these limitations, we used computer simulation of S shaped elastic rods to primarily show whether variations in the S-shaped curvature of a rod can produce different deformation patterns and secondarily whether those deformation patterns relate to the spinal deformity patterns in AIS. As our analysis showed a high level correlation between the rod and scoliotic patients 3D curve deformation pattern while only varying the sagittal curvatures of the rod. It was concluded that the shape of the sagittal curve, more specifically the length of the spine with kyphotic and lordotic curves can determine the spinal deformation patterns. This analysis can have significant implementation in sagittal classification of this spine.

Additional factors such as the properties of the stabilizing mechanism of the spine (muscle, ligament, intervertebral disc properties and their maturation rate) and growth rate, in relation to each other, can additionally play a role in induction of scoliosis. As the shape of the sagittal curve impacts the mechanical loading along the spine, an immature spine may not tolerate the mechanical loading and deform. The fast growth period can also impact the torsional loading of the spine as also shown in other growing tissues and plant, causing the spine to twist. Faster growth and lower rotation resistance of the spine can induce a twist in the spine that when combined with gravitational loading cause 3D off-plane deformation, i.e. scoliosis. While mechanically it can be explained why the kyphotic and lordotic curves rotate in opposite directions [3,4], the direction of the thoracic and lumbar curve deformity (i.e. right thoracic/left lumbar versus left thoracic/right lumbar) is dictated by the trunk mass asymmetry explaining opposing curve patterns in situs versus patient compared to general population (Figure 3).

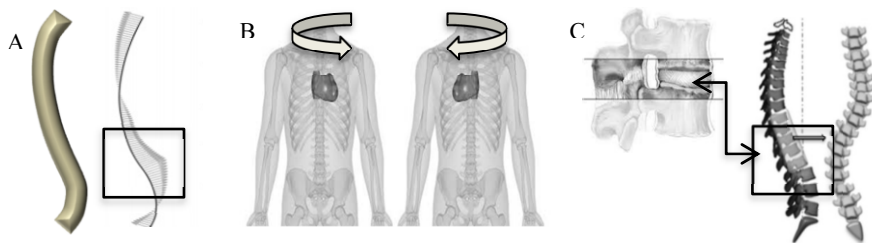


Figure 3. Pathomechanism of the curve development in AIS: A) Shape of the sagittal curvature impacts the mechanical loading of the spine (induced by the trunk weight and growth) resulting in different places of maximum moments. B) Internal organs determine the handedness of coiling (tendency to right or left) C) When the forces/moments are not tolerated with stabilizing mechanisms spine deforms in 3D.

## Conclusion and Significance

The shape of the sagittal curve relates to the deformation patterns of the spine in AIS patients. The role concurrent spine maturation and fast growth at the onset of spinal deformity development in AIS and whether how a mismatch between these two natural changes in the spine can impact the mechanics of a 3D loaded spine and lead to scoliosis merits further investigations.

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# Role of differentially expressed *LBX1* in Adolescent Idiopathic Scoliosis (AIS) paraspinal muscle phenotypes and muscle-bone crosstalk through modulating myoblasts

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**Abstract:** AIS is three-dimensional spinal deformity with unclear etiopathogenesis. *LBX1* is so far the only multi-centers validated AIS predisposing gene. The imbalance of posterior paraspinal muscles is an important factor in AIS etiopathogenesis. It is poorly understood how *LBX1* contributes to the abnormal paraspinal muscles and onset/progression of AIS. We aimed to evaluate the expression of *LBX1* in paraspinal muscles at the concave and convex side in AIS, and whether alternation of *LBX1* expression could affect myoblasts activities and potentially influence muscle-bone interaction via myokines expression. Paraspinal muscles from AIS and age- and curvature-matched congenital scoliosis (CS) patients were collected for fiber types analysis. Biopsies were also subjected to qPCR to validate expression of myogenic markers, selected myokines and *LBX1*. Human skeletal muscle myoblast (HSMM) was used for *LBX1* loss-of-function study in vitro. Muscle fiber types analysis showed type I and type IIX/IIAX fibers proportion were significantly different between AIS concave and convex but not in two sides of CS. *LBX1*, myogenic markers and one myokine were significantly imbalanced in AIS but not in CS. Loss-of-function study showed knockdown of *LBX1* could inhibit myogenic markers expression and myokines as well. This study provides new insight into the association between imbalanced paraspinal muscle and potential muscle-bone crosstalk in AIS patients and the biological function of predisposing gene *LBX1*. Further investigation with appropriate animal models is warranted to explore if asymmetric expression of *LBX1* could result in distinct muscle phenotypes and bone qualities thus affect the progression of spine curvature in AIS.

**Keywords:** AIS, *LBX1*, skeletal muscles, myokines

## Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity affecting 1-4% of adolescent worldwide. Unlike congenital, neuromuscular and other

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types of scoliosis, the etiopathogenesis of AIS remains unclear. It has been shown that posterior paraspinal muscles could provide dynamic stability to the spinal column 1. Histological analysis demonstrated fibrosis and fatty infiltration in posterior paraspinal muscles and their discrepancy between concave and convex sides in AIS patients 2,3, suggesting the likelihood of different degrees of muscle regeneration between two sides. Moreover, muscle fiber types analysis reported an asymmetry of fiber types distribution between concave and convex sides paraspinal muscles. The imbalance has been postulated to contribute to the initiation and/or progression of spinal deformity in AIS, however, the mechanism underlying is still unclear.

Genetics is one of the proposed pathomechanisms of AIS and rs11190870 is the most suspected single nucleotide polymorphism (SNP) associating with AIS verified by multicenter studies which locates at the downstream of promoter region of *ladybird homeobox 1 (LBX1)* gene 4. Overexpressing *LBX1* by microinjection of the transcripts in zebrafish embryos could cause body axis deformation during embryonic stage 5. In mouse, *Lbx1* was highly expressed in activated satellite cells, and gradually decreased when satellite cells were differentiation into mature myofibers 6. To our knowledge, the biological function of *LBX1* in human myoblast and its potential association with muscle phenotypes in AIS have not been addressed yet.

In this study, we hypothesized that *LBX1* differentially expresses in AIS concave Vs convex sides paraspinal muscles at apex, and such discrepancy modulates imbalanced paraspinal muscle phenotypes and muscle-bone crosstalk via regulating myoblast activities.

## Methods

AIS and age- and curve severity-matched CS patients were recruited. Posterior paraspinal muscles on concave and convex sides of apex of the major curve were harvested during surgery after obtaining informed consent. Muscle biopsies were cryo-sectioned for fiber types distribution analysis with myosin heavy chain (MHC) immunofluorescence (IF) staining. Total RNA was extracted from paraspinal muscles for qPCR analysis to evaluate expression of *LBX1*, myoblast myogenic markers and selected myokines. Spearman correlation analysis was conducted between *LBX1* and selected markers expression. HSMM cells were used for loss- of-function study. *LBX1* knockdown (KD) was performed by transfecting HSMM with small interfering RNA (siRNA). The myogenic markers, myokines and myosin heavy chain isoforms expression was determined after myogenic induction.

## Results and Discussion

AIS (N=26) and CS (N=13) groups had similar age (11-15 years) and Cobb angle (35-92 degree) at their first clinical visit. There was significantly higher *LBX1* expression in AIS convex side than in concave side (Figure 1). And the difference between CS two sides did not reach significance. Key myogenic genes representing muscle stem cell activities, such as *PAX7* (paired box 7), *PAX3* (paired box 3), *MYOG* (myogenin) and *MYF6* (myogenic factor, also known as *MRF4*), and one of the selected myokines, *apelin* had significantly differential levels between AIS concave Vs convex

paraspinal muscles at the apex of major curve, however, were less observed between CS concave and convex sides. LBX1 showed significantly positive correlation with markers PAX7, MYOD1 (myogenic differentiation 1), MYOG, MYF5 (myogenic factor 5) and ACTA1 (actin alpha 1) in AIS paraspinal muscles which was not observed in CS group. Cross-sectional area (CSA) analysis of MHC staining showed that there was significant lower proportion of muscle fiber type I on AIS concave side compared with the convex side and the difference was not significant between CS concave and convex paraspinal muscles. In loss-of-function study, the KD was confirmed on mRNA level on baseline (D0) and after four days myogenic differentiation (D4) by comparing with negative control HSMM cells (NC) (Figure 2). The baseline expression of LBX1 did not show significant decreasing while the LBX1 expression on D4 was significantly knocked down. Myogenic markers including PAX7, MYOG, MYF5, ACTN2 (actinin alpha 2) and TNNT3 (troponin T3) were showed to have significantly lower expression in KD cells than NC cells after four days of differentiation. The expression of selected myokines were also altered after LBX1 KD.

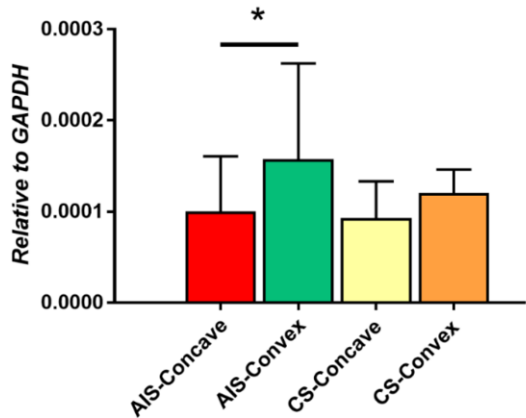


Figure 1. Transcriptional level of LBX1 in paraspinal muscles. N=24/side for AIS, n=9/side for CS. Data is shown with mean ± SD. Mann-Whitney U is used. \* p-value <0.05.

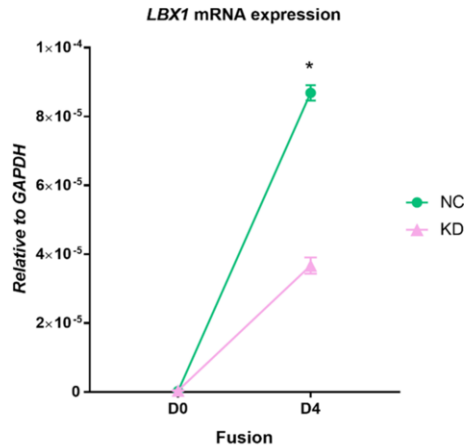


Figure 2. Transcriptional level of LBX1 in loss-of-function study. N=3/group. Result is shown with mean ± SD. Mann-Whitney U is used. \*p-value <0.05.

## Conclusion and Significance

By comparing with age- and curve severity-matched CS patients to minimize the potential confounding effect of spinal asymmetry, our study demonstrated that there was differential paraspinal muscle fiber types distribution and myogenic makers expression pattern in AIS patients which was not likely to be solely affected by spinal deformity. The LBX1 mRNA expression in AIS concave and convex sides paraspinal muscles and the modulating effect of LBX1 on myoblasts myogenesis as well as myokines levels further provide evidence of the association between asymmetric LBX1 expression with imbalance paraspinal muscle phenotypes in AIS. There are still questions not adequately answered in this study. 1, What causes the differential expression of LBX1 in AIS apical paraspinal convex and concave muscles? 2, Could the differential muscle phenotypes cause the initiation/progression of AIS? Further investigation with appropriate animal models is warranted to help us reveal the possible pathogenic roles of LBX1 in scoliosis onset and progression.

## Acknowledgement

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# Variations in the sagittal plane precede the development of scoliosis: a proof of concept

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**Abstract:** Idiopathic scoliosis in man is believed to be related to the unique human sagittal profile. Patients with a thoracic scoliosis have a longer, more proximal, posteriorly inclined segment of the spine as compared to lumbar scoliosis and controls, whereas patients with a lumbar scoliosis have a more caudal, shorter and steeper posteriorly inclined segment. In 22q11.2 deletion syndrome, half of the patients develop a scoliosis that is very similar to idiopathic scoliosis and may serve as a model for the general population. In our center, all patients with 22q11.2 deletion syndrome older than 6 years receive standardized radiographic spine imaging every 2 years to screen for scoliosis. In this prospective proof-of-principle study the goal was to determine whether there are differences in sagittal alignment between patients that develop scoliosis vs. controls before the onset of scoliosis, and obtain data to perform a power calculation for future studies. To capture the sagittal shape of the spine into one risk factor for development for scoliosis, we combined relative length and magnitude of dorsal inclination into a new parameter: the posterior inclined triangle surface (PITS). We included 31 patients with initially straight spines, five developed a thoracic scoliosis and seven developed a (thoraco)lumbar scoliosis after a mean follow-up of 3.4 years. The PITS was considerably higher in the group that developed scoliosis as compared to the controls (59 vs 43). Based on this pilot study, we have identified a potential overall sagittal profile risk parameter for the development of idiopathic scoliosis.

**Keywords:** Idiopathic scoliosis, sagittal profile, PITS, risk factor

## Introduction

Idiopathic scoliosis in man is believed to be related to the unique human sagittal profile.[1-6] Patients with a thoracic scoliosis have a longer, more proximal, posteriorly inclined segment of the spine as compared to lumbar scoliosis and controls, whereas patients with a lumbar scoliosis have a more caudal, shorter and steeper posteriorly inclined segment.[7] One of the main problems in etiological scoliosis research is the paucity of data on scoliosis patients before the onset, that is, it is unknown whether associated factors are causative to the development of scoliosis.

In order to overcome this, we follow patients with the 22q11.2 deletion syndrome (22q11.2DS) prospectively from before the onset of any spinal deformity. In 22q11.2DS half of the patients develop a scoliosis that is very similar to idiopathic scoliosis and may



serve as a model for the general population.[8,9] The goal of this prospective proof-of-principle study is to determine whether there are differences in sagittal alignment between patients that develop scoliosis vs. controls before the onset of scoliosis, and obtain data to perform a power calculation for future studies.

Materials & Methods

All patients with 22q11.2DS (age≥6 years) receive standardized radiographic spine imaging every 2 years to screen for scoliosis. After IRB approval, we obtained data of all children with 22q11.2DS that were followed radiologically for ≥1 year. Patients with congenital abnormalities or deformities at baseline were excluded. Sagittal spinal alignment was analyzed using Surgimap Spine software (Nemaris, New York) according to a previously validated protocol.[7] The sagittal spinal parameters were determined on the first radiograph (at initial presentation, before the potential development of scoliosis). The radiographic parameters are shown in Figure 1.

Global spinal parameters		
Thoracic kyphosis	TK	This angle is measured from the upper end plate of T4 to the lower endplate of T12 using the Cobb method
Lumbar lordosis	LL	This is angle is measured from the upper endplate of T12 to the endplate of S1 using the Cobb method.
Inclination of the spine		
Number of declive vertebrae	#DV	Number of vertebrae of which the inferior endplate is posteriorly inclined as compared to the horizontal (in this figure the vertebrae from A till B).
Declive length	DL	Length of the part of the spine that is posteriorly inclined segment, normalized for T1-L5
Declive segment inclination	DI	Angle between a line through the centroids of the cranial and caudal end level of the part of the spine that is posteriorly inclined and the vertical (in this figure β).
Posterior inclined triangle surface	PITS	The posterior inclined triangle surface (PITS) is depicted with the white dashed line and was calculated by using DL and DI: $\frac{1}{2} * ((\sin(\beta) * DL) * (\cos(\beta) * DL))$
Pelvic parameters		
Pelvic incidence	PI	Angle between the perpendicular to the sacral plate and the line connecting the sacral end plate midpoint to the hip axis.
Pelvic tilt	PT	Angle between the line connecting the midpoint of the sacral plate to the hip axis, and the vertical.
Sacral slope	SS	Angle between the superior end plate of S1 and the horizontal.



Figure 1. Radiographic parameters. In this figure, the radiographic parameters are shown. To identify a single value that predicts onset of scoliosis (irrespective of apex height) or not, the surface of the triangle defined by the posterior inclined segment (PITS) was calculated as a measure of the overall magnitude of the posteriorly acting shear loads.

Based on the most recent posterior-anterior radiograph, patients fell into the nonscoliotic control group (no curve≥10 degrees), thoracic scoliosis group (between T2

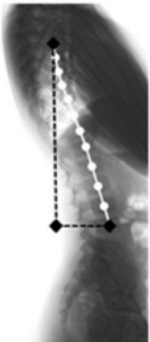
and T11–T12 disk) or (thoraco)lumbar scoliosis group (T12 or more caudal).[10] Since this is a pilot study only descriptive statistics were used.

Results and Discussion

We included 31 22q11.2DS patients with initially straight spines, five developed a thoracic scoliosis and seven developed a (thoraco)lumbar scoliosis (mean coronal curve angle 19 and 16 degrees, respectively), after a mean follow-up of 3.4 years (Figure 2).

	Means		
	No scoliosis	thoracic scoliosis	(thoraco)lumbar scoliosis
	N=19	N=5	N=7
Pelvic parameters			
Pelvic incidence (°)	38.6° (SD:11.9)	36.3° (SD:4.4)	50.9° (SD:33.6)
Pelvic tilt (°)	5.8° (SD:6.7)	7.4° (SD:5.9)	16.3° (SD:32)
Sacral slope(°)	32.8° (SD:10.5)	28.9° (SD:5.7)	34.6° (SD:8.4)
Global spinal parameters			
Thoracic kyphosis (°)	28° (SD:11.6)	28° (SD:5.4)	32° (SD:7.7)
Lumbar lordosis (°)	48° (SD:11.7)	47° (SD:7.8)	56° (SD:8.5)
Inclination of the spine			
Number of declive vertebrae	9.3° (SD:2)	11° (SD:1.2)	10.1° (SD:0.9)
Declive length (ratio)	0.551 (SD:0.123)	0.664 (SD:0.092)	0.593 (SD:0.071)
Declive inclination (°)	15.9° (SD:4.6)	16.7° (SD:2.1)	19.7° (SD:6.5)
Posteriorinclined triangle surface (Area)	43 (SD: 22)	62 (SD: 18)	57 (SD:23)

Thoracic scoliosis



(thoraco)lumbar scoliosis




Figure 2. Means of the spino-pelvic sagittal parameters. The two radiographs show the differences between thoracic and (thoraco)lumbar scoliosis. Thoracic scoliosis patients have a longer, more proximal, posterior inclined segment. Lumbar scoliosis patient have a steeper, shorter, posterior inclined segment. The patients with thoracic scoliosis had another shape of the posterior inclined triangle surface (PITS, triangle with black and white dashed lines) as compared to patients with lumbar scoliosis. SD, standard deviation.

Before the onset of scoliosis, patients with (thoraco)lumbar scoliosis had a shorter, more posteriorly inclined segment of the spine as compared to nonscoliotic and thoracic scoliotic patients: (thoracolumbar) scoliosis was 24% and 18% more inclined respectively. Conversely, patients with thoracic scoliosis had a longer and more cranially extending posteriorly inclined segment as compared to (thoracolumbar)scoliosis and controls: thoracic scoliosis was 12% and 21% longer respectively (Figure 2). To capture the sagittal shape of the spine into one risk factor for development for scoliosis, we combined relative length and magnitude of dorsal inclination into a new parameter: the posterior inclined triangle surface (PITS, Figure 1). This PITS was considerably higher in the group that developed scoliosis as compared to the controls (59, standard deviation: 20 vs 43, standard deviation: 22).

Until now, it is unknown if the sagittal shape precedes the scoliotic deformity, or coincides with it as part of the overall 3D decompensation mechanism. We believe this study shows strong indications for the initiating role of sagittal profile in development of scoliosis. This is most effectively reflected by the PITS which can be used for future studies to confirm the (causal) relation between the sagittal profile and scoliosis. For that purpose we would need a sample size of 50 patients with 22q11.2DS with adequate follow-up (Nominal Power 0.8,  $\alpha$  0.05).

## Conclusion and Significance

This is the first proof-of-principle of a prospective longitudinal study that indicates differences in sagittal spinal alignment between thoracic scoliosis, (thoraco)lumbar scoliosis and nonscoliotic children, before onset of the deformity. This study was performed in a cohort of patients with 22q11.2DS who are known to develop a scoliosis that strongly resembles idiopathic scoliosis [8,11]. We determined an overall sagittal profile risk parameter for the development of idiopathic scoliosis (PITS). Based on this pilot study, there is a difference in PITS for patients with scoliosis as compared to controls before the onset of scoliosis. These findings support the use of this methodology and provide information (data and a sample size calculation) for further powered studies.

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# Lower WNT16 expression in patients with adolescent idiopathic scoliosis – potential link to lower bone mass in AIS?

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**Abstract:** Adolescent Idiopathic Scoliosis (AIS) occurs during pubertal rapid growth period and is closely associated with low bone mass. The underlying mechanisms for systemic low bone mass in AIS remains unclear. Wnt signalling pathway is one of the important pathways regulating bone metabolism and influencing bone strength, its family member Wnt16 associates with lower bone mineral density (BMD) in late adulthood, and plays key regulatory role in determining cortical bone quality in adult mice. Our randomized control trial have reported vitamin D (VitD) supplementation significantly improved bone mass and reduced the risk of curve progression in AIS. A case-control study and animal study were employed to answer if WNT16 is associated with the abnormal bone quality in AIS and if the effect of VitD supplementation is associated with Wnt16, respectively. A cohort of 161 AIS and control female subjects were recruited for measurement of anthropometric parameters, bone qualities, and circulating Wnt16 level. In animal study, WT and Wnt16 gKO mice were both subjected to special VitD diet from week 4 and terminated at week 7 and 10 for samples harvesting. AIS showed significantly lower BMD, circulating WNT16 level, and elevated serum level of type I procollagen N-terminal propeptide. Wnt16 gKO mice demonstrated lower cortical bone density compared with WT mice from week 7 of age and Wnt16 gKO were less prone to cortical bone loss induced by high dosage VitD diet. Further study on the biological role of WNT16 and crosstalk with VitD metabolism on bone qualities is warranted which might shed light on prognostic gene of osteopenia and new perspectives for potential target to prevent curve progression.

**Keywords:** AIS, bone mass, BMD, Vitamin D, WNT16 expression

## Introduction

Adolescent Idiopathic Scoliosis (AIS) is a three-dimensional (3D) spinal deformity that occurs during pubertal growth spurt with multifactorial pathomechanisms underlying the initiation phase and progression phase. The prevalence rate of AIS differs across geographic latitude, sunlight exposure and countries, it affects adolescents

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between 1-4% and predominantly affects female.[1,2] Abnormal bone quality in AIS has been reported by many groups. Previously, our prospective study on 324 AIS girls with observation until skeletal maturity gave evidence to show osteopenia in the femoral neck could be a risk factor for curve progression, with an odds ratio of 2.3.[3] The association between bone mass and curve progression prompts us to investigate the mechanism underlying deranged bone quality change during rapid growth period and curve progression in AIS.

VitD is one of the important factors which has long been known to play an important role on skeletal growth, regulating calcium-phosphate homeostasis, and bone matrix mineralization.[4] VitD deficiency during the rapid growth period was associated with inadequate skeletal mineralization which leads to rickets and even osteoporosis.[5] Our group showed VitD insufficiency among adolescents in Hong Kong and found significant association with bone quality.[6] Our randomized double-blinded placebo-controlled trial has indicated that VitD supplementation could improve BMD and concurrently prevent curve progression in AIS girls with low bone mass. WNT signalling pathway is one of the crucial pathways involved in the regulation of bone metabolism and bone strength.[7] Meta-analysis on GWAS data indicated that Wnt family ligand 16 (WNT16) appears to have a positive effect on BMD and bone strength, mutation in Wnt16 exhibit similar systemic low BMD phenotype observed in AIS girls. Studies with transgenic mice with the deletion of WNT16 have demonstrated abnormal cortical bone qualities.

With these, we hypothesized that circulating WNT16 could be associated with bone quality in AIS. With our RCT study showing the beneficial effect of VitD supplementation on bone quality in AIS, transgenic Wnt16 global knockout mice was used to examine whether cortical bone quality would be affected during rapid growth phase in the absent of Wnt16, and to investigate whether different dosage of dietary VitD could affect cortical bone mass during the rapid growth phase.

## Methods

A total of 161 AIS participants (13.89 yrs (12.78, 15.00)) randomly recruited from the Scoliosis Clinic of The Prince of Wales Hospital and another 161 (13.84yrs (12.89, 15.15)) were recruited from secondary school in Hong Kong and serve as aged- and gender- matched healthy control. Standard posteroanterior X-ray radiograph and Cobb angle measurements were used to classify the AIS and non-AIS group. Standardized stadiometric method were used to assess anthropometric parameters including body weight, standing height, sitting height and arm span.[8] Pubertal stage was self-reported with a diagram indicating different Tanner stages.[9] Right and left sided bilateral femoral neck were used to assess aBMD with DXA (Hologic, Horizon DXA System, Marlborough, USA) and is expressed as  $\text{g}/\text{cm}^2$  calculated from measured bone mineral content (BMC) in grams divided by the detected bone area in  $\text{cm}^2$ . [2,10] Z-score of  $\leq -1$  is regarded as osteopenia. Non-dominant distal radius was used for the 3D assessment on bone quality with HR-pQCT (XtremeCT, Scanco Medical, Brüttisellen, Switzerland). A protocol of the relative offset distance started at 4% of the ulnar length was used to set the reference line for the starting point for each scan.[11] Peripheral venous blood was collected. The serum concentration of markers including osteocalcin (OCN), tumor necrosis factor alpha (TNF $\alpha$ ), sclerostin (SOST), dickkopf-related protein 1 (DKK-1), osteoprotegerin (OPG) and osteopontin (OPN) were assayed with multiplex assay from

Luminex xMAP Multiplexing technology (EMD Millipore, Billerica, MA). The serum concentration of CTX and PINP were sent out to medical laboratory for assay (Chan & Hou Medical Laboratories Ltd.) The plasma concentration of WNT16 was measured by ELISA assay with standard protocol provided by the manufacturer (Cusabio, Houston, USA).

Wnt16 knockout mice (gKO) were generated with the disruption of the first 3 exons in a C57BL6/J-129SvEv hybrid genetic background. Homozygous Wnt16<sup>+/-</sup> mice (WT) were used as control. VitD deficient chow (0 IU/Kg) (VDD) (Diet#SF03-009), VitD sufficient chow (1000 IU/Kg) (Ctrl) (Diet#AIN93G) and high dosage of VitD chow (20,000 IU/Kg) (HDV) (Diet#SF17-207) were purchased from Specialty Feeds, Western Australia. WT and gKO mice were subjected to different vitamin D diet from week 4 and sacrificed at week 7 and 10. High-resolution 3D MicroCT 40 ( $\mu$ CT-40, Scanco Medical, Brttisellen, Switzerland) was used to scan and quantify the cortical bone of the femoral midshaft. Bone area (BArea), bone volume to tissue volume ratio (BV/TV), cortical thickness (Ct.Th) and tissue density (TVdensity) were determined.

The data were expressed in either Mean  $\pm$  SD or median with lower quartile and upper quartile. Kolmogorov-Smirnov test was used to test for data normality. Normally distributed data was tested with two-tailed student t-test to examine the difference between groups, or else Mann-Witney U test was used. Serological data were log e transformed for comparison and correlation analysis. Correlation between different bone quality parameters and circulating expression of bone markers were performed with Pearson or Spearman's rho tests on normally and not normally distributed variables respectively. Statistical analysis was conducted with SPSS software version 23.0 (IBM Corp., NY) with significance level set at  $p < 0.05$  (2-tailed).

## Results and Discussion

AIS showed significantly lower Z-score on bilateral femoral necks compared to control (both left and right sided with  $p$ -value  $< 0.001$ ). Bone morphometric and vBMD results from the HR-pQCT assessments indicated significantly lower total vBMD ( $p$ -value  $< 0.001$ ) in AIS compare to healthy control. Cortical compartments also indicated significantly lower cortical area, vBMD ( $p$ -value  $< 0.001$ ) and thickness ( $p$ -value = 0.001) in AIS girls compare to healthy control. Table 1 shows AIS had statistically lower plasma WNT16 ( $p$ -value = 0.034) level compared with the control. AIS girls showed higher serum PINP ( $p$ -value = 0.015) and sclerostin ( $p$ -value  $< 0.001$ ) concentration than healthy control. Correlation analysis between circulating bone markers and average bone quality parameters showed serum CTX, PINP, OCN and OPN levels were significantly and negatively correlates with DXA z-score in both AIS and control group (range from  $r = -0.198$  to  $-0.514$  and  $r = -0.203$  to  $-0.567$  in AIS and control, respectively) Serum level of sclerostin in healthy control group was significantly associated with DXA z-score ( $r = -0.176$  and  $r = -0.178$  in left and right, respectively), which is not seen in AIS patients. Total vBMD significantly correlates with serum DKK1 level ( $r = 0.157$ ) in AIS, whereas correlates with serum TNF $\alpha$  and SOST ( $r = -0.224$  and  $r = 0.011$ , respectively) in control. Differential correlation patterns between AIS and healthy control indicates impaired metabolic bone cell activities in AIS.

Table 1. Comparison of circulating markers in AIS vs healthy control

	AIS (N=161)	Control (N=161)	p-value
WNT16 <sup>a</sup>	3.86 (3.32, 4.59)	4.37 (3.81, 4.77)	0.034
CTX <sup>b</sup>	6.53 ± 0.63	6.47 ± 0.60	0.127
P1NP <sup>a</sup>	5.75 (5.18, 6.39)	5.42 (4.90, 6.12)	0.015
OCN <sup>a</sup>	9.98 (9.73, 1.054)	9.97 (9.51, 10.44)	0.183
TNFα <sup>a</sup>	0.82 (0.55, 1.07)	0.87 (0.61, 1.13)	0.059
SOST <sup>a</sup>	7.14 (6.94, 7.37)	6.97 (6.73, 7.18)	<0.001
DKK-1 <sup>b</sup>	7.38 ± 0.25	7.43 ± 0.28	0.075
OPG <sup>b</sup>	5.54 ± 0.21	5.55 ± 0.23	0.899
OPN <sup>b</sup>	9.34 ± 0.69	9.48 ± 0.57	0.058

a: Mann-Whitney U test presented as median (lower quartile, upper quartile) b: Independent sample t-test presented as Mean ± SD/ The level of C-telopeptide of type I collagen (CTX) and type I procollagen N-terminal propeptide (P1NP) in serum are represented as µg/L. The levels of wnt family member 16 (WNT16), osteocalcin (OCN), tumor necrosis factor – alpha (TNFα), sclerostin (SOST), diekkopf-1 (DKK-1), osteoprotegerin (OPG), and osterpontin (OPN) are represented as pg/mL. Serum bone turnover markers data were natural log transformed before calculation to enhance normality.

Wnt16 gKO mice had lower cortical bone density compared with WT mice. At the age of week 7, cortical bone area (p = <0.001), bone volume over total volume ratio (p = 0.011), thickness (p = <0.001) and density (p = 0.021) were significantly reduced in Wnt16 gKO mice compared with WT mice. By the age of week 10, the gKO mice exhibited significantly lower cortical bone area, bone volume over total volume ratio, thickness and density (p = <0.001) (Figure 1). Wnt16 gKO mice had lower cortical bone mass compared with WT mice in VitD deficient group (Figure 2). High dosage VitD group retained cortical bone density in Wnt16 gKO mice (Figure 3). We observed optimal VitD effect on cortical bone accrual at sufficient dosage, and the negative effect of high dosage of VitD supplementation was diminished in the absence of Wnt16.

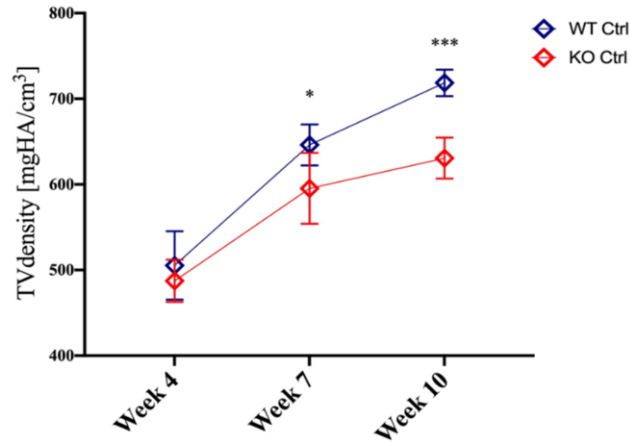


Figure 1. Line graphs of the micro-CT analysis on cortical bone at midshaft femur in WT and WNT16 gKO mice. Mann-Whitney U test, presented as Mean ± SD. TVdensity, cortical tissue density.



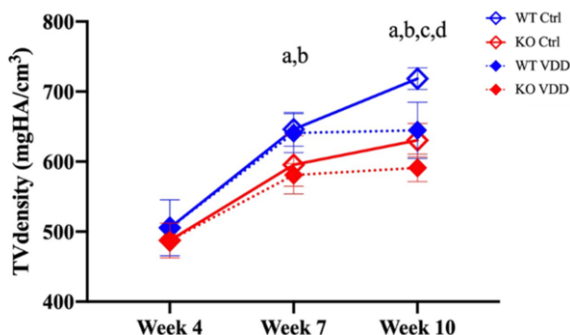


Figure 2. Line graph of micro-CT analysis on cortical bone at the midshaft femur of WT and WNT16 gKO on VitD sufficient or VitD deficient group. a,b,c, and d indicate a significant different between WT Ctrl and KO Ctrl, WT VDD and KO VDD, WT Ctrl and WT VDD, KO Ctrl and KO VDD respectively. Mann-Whitney U test, presented as Mean  $\pm$  SD. TVdensity, cortical tissue density.

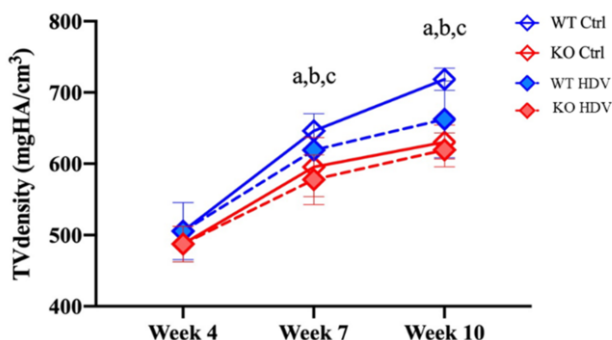


Figure 3. Line graph of microCT analysis on cortical bone at the midshaft femur of WT and WNT16 gKO in VitD sufficient or high dosage. a,b,c, and d indicate a significant different between WT Ctrl and KO Ctrl, WT HDV and KO HDV, WT Ctrl and WT HDV, KO Ctrl and KO HDV respectively. Mann-Whitney U test, presented as Mean  $\pm$  SD. TVdensity, cortical tissue density.

## Conclusion and Significance

To the best of our knowledge, this is the first study demonstrating the reduced plasma level of WNT16 in AIS vs healthy control participants and indicating the possible role of WNT16 in regulating abnormal cortical bone mass and structure in AIS. Wnt16 gKO mice demonstrated lower cortical bone vBMD, thickness and bone volume ratio when compared with WT mice, which supported its biological role in cortical bone accrual. In WT mice, sufficient dietary VitD seems to be an adequate dosage to render beneficiary effect on cortical bone accrual in contrast to the negative effect observed in deficient and high dose dietary groups. On the other hand, Wnt16 gKO mice appeared to be less vulnerable to cortical bone loss upon high dosage of dietary VitD treatment. Further validation studies on the biological role of Wnt16 and crosstalk with VitD metabolism on cortical and trabecular bone qualities should be warranted. Further investigation with conditional knockout transgenic animal models and molecular functional studies in cellular models, such as osteoblast and osteoclast could be used to facilitate

comprehensive understanding in causal relationship between imbalanced bone cells activities and derange bone qualities in patients with AIS.

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# Chapter 2

## Growth and Metabolism

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# A six years longitudinal cohort study on the changes in bone density and bone quality up to peak bone mass in adolescent idiopathic scoliosis (AIS) with and without 2 years of Calcium and Vit-D supplementation

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**Abstracts:** Adolescent idiopathic scoliosis (AIS) is associated with osteopenia which could persist into adulthood affecting attainment of Peak Bone Mass thus resulting in osteoporosis in late adulthood. We previously reported a randomized double-blinded placebo-controlled trial(the Cal study) showing significant bone health improvement with 2-year calcium(Ca)+Vit-D supplementation for AIS girls. This study addressed the important issue whether bone health improvement from the initial 2-year Ca+Vit-D supplementation could persist as subjects approached towards Peak Bone Mass at 6-year ie after 4-year of supplement discontinuation. This was an extension of the Cal study on AIS girls (11-14 years old, mean age=12.9 years, Tanner stage<IV) with femoral neck aBMD Z-score<0 and Cobb angle≥15°. 330 subjects were randomized to Group1(placebo), Group2(600mgCa+400-IU-Vit-D<sub>3</sub>/day) or Group3(600mgCa+800-IU-Vit-D<sub>3</sub>/day) for 2-year supplementation after which supplementation was stopped. Investigations at baseline, 2-year and 6-year included High-resolution Peripheral Quantitative Computed Tomography(HR-pQCT) at distal radius and Dual Energy X-ray Absorptiometry(DXA) at both hips. 270(81.8%) subjects completed 2-year supplementation when changes in left femoral neck aBMD, trabecular vBMD, Trabecular BV/TV, Trabecular Number and Trabecular Separation indicated significant bone health improvement with Ca+Vit-D supplementation(p<0.05). At 6-year(mean age=19.2 years), no between-group difference on bone parameters was noted except increase in Cortical Thickness being greater only in Group3 than in Group1. After 4-year supplement discontinuation, the treatment effect from the initial 2-year supplementation mostly dissipated indicating the need of continued supplementation in AIS girls to sustain therapeutic improvement on bone health as subjects approach towards Peak Bone Mass.

**Keywords:** Adolescent Idiopathic Scoliosis, bone health, Vitamin D, Peak Bone Mass

## Introduction

Adolescent Idiopathic Scoliosis (AIS) is a complex three-dimensional spinal deformity mostly affecting girls during the peri-pubertal period. 30-38% of AIS girls have osteopenia (BMD Z-score < -1) which could persist into adulthood resulting in suboptimal Peak Bone Mass which has been reported to be an important determinant predisposing to subsequent osteoporosis and disabling complications in late adulthood.

Optimal bone mineralization for attainment of satisfactory Peak Bone Mass across puberty is therefore of paramount importance. Vit-D regulates calcium absorption and plays an important role in skeletal growth and bone mineralization critical for achieving optimal Peak Bone Mass. Given that AIS girls have been reported to have low dietary calcium intake and high prevalence of Vit-D insufficiency, our group has previously reported a 2-year randomized double-blinded placebo-controlled trial investigating the therapeutic effect of calcium (Ca) and Vit-D supplementation for low bone mass in AIS girls (the Cal study). In the Cal study, AIS girls were randomized to either Group 1 (placebo), Group 2 (600mg Calcium+400 IU Vit-D<sub>3</sub>/day) or Group 3 (600mg Calcium+800 IU Vit-D<sub>3</sub>/day). Upon 2-year of supplementation treatment, the study did show strong evidences of positive bone accretion effects explicitly observed in the Treatment Groups (i.e. Group 2 and Group 3) as compared with the Placebo Group (Group 1).

The importance of optimizing Peak Bone Mass during pubertal growth cannot be overemphasized. One clinically important question to ask is whether the therapeutic gain in bone mineral density (BMD) and bone quality with 2-year supplementation of Ca+Vit-D could persist after 4-year discontinuation of treatment as the subjects in the Cal study approach towards their Peak Bone Mass. We therefore carried out an extension of the Cal study by prospectively following the cohort up to Peak Bone Mass. Our objective is to compare the changes in bone mineral density (BMD) and bone quality in AIS girls between Group 1, 2 and 3 respectively at the completion of 2-year Ca+Vit-D supplementation and after 4-year of supplement discontinuation. The data will be analyzed together with the data from the Cal study thus constituting a total of 6-year prospective longitudinal follow-up.

## Methods

This was a randomized double-blinded placebo-controlled trial on AIS girls (11-14 years old, mean age = 12.9 years, Tanner stage < IV) with femoral neck aBMD Z-score < 0 and Cobb angle ≥ 15°. 330 subjects were randomized to Group 1(placebo), Group 2(600mgCalcium+400IUVit-D<sub>3</sub>/day) or Group 3(600mg Calcium+800IUVit-D<sub>3</sub>/day) for 2-year treatment after which treatment was stopped. Clinical follow up was continued for at least 4 years after cessation of supplementation. Investigations were done at baseline (ie at the start of supplementation), 2-year (ie at completion of 2-year supplementation) and 6-year (ie after 4 years of cessation of supplementation). Investigation included High-resolution Peripheral Quantitative Computed Tomography (HR-pQCT) at non-dominant distal radius and Dual Energy X-ray Absorptiometry (DXA) at proximal hips. Serum 25(OH)Vit-D level was assayed with liquid chromatography tandem mass spectrometry. Intention-to-Treat principle was followed on those who have completed 2-year treatment. ANCOVA was used for analysis. A p-value < 0.05 was considered statistically significant.

## Results and Discussion

The baseline data of mean age, serum 25(OH)Vit-D level, DXA and HR-pQCT parameters are shown in Table 1. No significant difference was noted between Group 1, 2 and 3 (all with  $p>0.05$ ).

Table 1: Baseline data on age, serum 25(OH)Vit-D levels, DXA, and HR-pQCT Parameters

	mean $\pm$ SD at baseline			p <sup>#</sup>
	Gp 1 (N=110)	Gp 2 (N=110)	Gp 3 (N=110)	
Age	13.0 $\pm$ 0.9	12.9 $\pm$ 0.9	12.7 $\pm$ 0.9	0.142
Serum 25(OH)Vit-D (nmol/L)	41.4 $\pm$ 13.3	42.3 $\pm$ 14.3	39.4 $\pm$ 15.4	0.306
Right Femoral Neck aBMD (g/cm <sup>2</sup> )	0.694 $\pm$ 0.064	0.681 $\pm$ 0.068	0.677 $\pm$ 0.065	0.126
Left Femoral Neck aBMD (g/cm <sup>2</sup> )	0.683 $\pm$ 0.059	0.677 $\pm$ 0.071	0.673 $\pm$ 0.066	0.500
Cortical Area in mm <sup>2</sup>	23.6 $\pm$ 10.5	21.3 $\pm$ 11.4	21.1 $\pm$ 11.4	0.248
Trabecular Area in mm <sup>2</sup>	151.4 $\pm$ 31.2	148.8 $\pm$ 31.2	150.6 $\pm$ 26.7	0.830
Cortical Thickness in mm	0.42 $\pm$ 0.20	0.40 $\pm$ 0.24	0.38 $\pm$ 0.22	0.480
Cortical Perimeter in mm	55.1 $\pm$ 0.5	54.5 $\pm$ 4.8	54.8 $\pm$ 4.0	0.650
Average vBMD in mg HA/cm <sup>3</sup>	243.3 $\pm$ 43.4	238.1 $\pm$ 51.0	235.8 $\pm$ 46.8	0.547
Compact Bone vBMD in mg HA/cm <sup>3</sup>	679.3 $\pm$ 74.2	663.6 $\pm$ 85.9	661.0 $\pm$ 85.1	0.268
Trabecular vBMD in mg HA/cm <sup>3</sup>	142.7 $\pm$ 23.1	139.6 $\pm$ 25.2	140.3 $\pm$ 25.6	0.671
Trabecular Bone Volume to Tissue Volume Ratio	0.119 $\pm$ 0.019	0.166 $\pm$ 0.021	0.117 $\pm$ 0.021	0.674
Trabeculae Number /mm	1.68 $\pm$ 0.20	1.69 $\pm$ 0.23	1.67 $\pm$ 0.23	0.822
Trabecular Thickness in mm	0.071 $\pm$ 0.009	0.069 $\pm$ 0.009	0.070 $\pm$ 0.008	0.308
Trabecular Separation in mm	0.534 $\pm$ 0.079	0.536 $\pm$ 0.102	0.541 $\pm$ 0.087	0.861

<sup>#</sup>: p-value from analysis using one-way ANOVA test

At 2-year time-point, 270 subjects (81.8% of the initial cohort) completed the 2-year treatment. The mean drug compliance with treatment was 83% as determined by count-back tablets remaining in the jar at the end of each 3-month period. The gain in serum 25(OH)Vit-D in both Treatment Group 2 and 3, and the gain in left femoral neck aBMD in Treatment Group 3 were significantly greater than the Placebo Group 1 (all with  $p<0.05$ ). Changes in Trabecular vBMD, Trabecular Bone Volume to Tissue Volume Ratio and Trabecular Number were different between groups demonstrating therapeutic enhancement of bone health with Ca+Vit-D supplementation in the Treatment Group 2 and 3 as compared with the Placebo Group 1 (all with  $p<0.05$ ). In contrast, the increase in Trabecular Separation was significantly greater in the Placebo Group 1 than Treatment Group 2 and 3.

At 6-year time-point, 226 subjects (83.7% of those who completed the 2-year treatment, or 68.5% of the initial cohort) were available for study at a mean age of 19.2 years old. In contrast to the 2-year time-point, at 6-year follow up after 4-year supplement discontinuation, no difference was noted in all DXA and HR-pQCT bone density and bone quality parameters except increase in Cortical Thickness being greater only in Treatment Group 3 than in Placebo Group 1.

## Conclusion and Significance

The results provided strong evidences that daily 600mgCa+400/800-IU-Vit-D<sub>3</sub> was effective for treating low bone mass in AIS subjects with Z-score<0 resulting in increase

in aBMD at left femoral neck and Trabecular vBMD and other bone micro-architecture parameters at non-dominant distal radius.

In contrast, at 6-year follow up with 4-year discontinuation of supplementation, the treatment effect seen with 2-year supplementation mostly regressed towards the null hypothesis.

After 4-year supplement discontinuation, the treatment effect from the initial 2-year supplementation mostly dissipated indicating the need of continued supplementation in AIS girls to sustain therapeutic improvement on bone health as subjects approach towards Peak Bone Mass.

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## Chapter 3

# Imaging and 3D Measurements: Radiography, CT-Scan, and MRI

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# Morphological changes of intervertebral disc in relation with curve severity of patients with Adolescent Idiopathic Scoliosis – a T2-weighted MRI study

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**Abstract:** The purpose of this study was to evaluate the morphological changes of intervertebral discs (IVD) and vertebral bodies (VB) in AIS girls according to the subgroups with different curve severity by magnetic resonance imaging (MRI). This study included 33 age-matched female controls and 76 AIS girls with a right-sided thoracic curvature. Wedge angle, height ratio and distance ratio of VB and IVD were measured on the best midline coronal and sagittal planes from reformatted MRI spine. Volumes of VB, IVD and nucleus pulposus (NP) were evaluated on volumetric images. One-way ANOVA with Bonferroni correction was used. There was significant difference in wedge angle and height ratio of VB and IVD between AIS and controls. In severe-AIS, the position of NP was significantly shifted to the convexity when compared with non-severe AIS and controls. Whereas, the volume of IVD and NP in severe-AIS was found to be significantly smaller. On top of coronal wedging of VB and IVD, there was significantly reduced volume of IVD and NP in severe-AIS patients, despite T2 signal of IVD was preserved. The current findings indicate that early mechanical effects on the discs and vertebrae in adolescent scoliotic spine is evident on quantitative imaging. Importantly, these patients may be vulnerable to disc degeneration if no operative treatment is prescribed.

**Keywords:** Intervertebral disc; Nucleus pulposus; Magnetic Resonance Imaging; Adolescent idiopathic scoliosis

## Introduction

In our earlier work, we found that there was significantly reduced spinal cord to vertebral column ratios in adolescent idiopathic scoliosis (AIS) patients with severe curve, suggesting a disproportional growth between the skeletal and the neural systems.[1-3] Subsequently, we proved that vertebral bodies (VB) wedging had less contribution to the anterior-posterior length discrepancy than the intervertebral discs (IVD) in increasing the severity of AIS.[4,5] However, the morphological changes on IVD has not been fully investigated. The purpose of this study was to evaluate the

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morphological changes of intervertebral discs (IVD) and vertebral bodies (VB) in adolescent idiopathic scoliosis (AIS) girls according to the subgroups with different curve severity by magnetic resonance imaging (MRI).

**Methods**

This study included 33 age-matched female controls and 76 AIS girls with a right-sided thoracic curvature. Wedge angle, height ratio and distance ratio of VB and IVD were measured on the best midline coronal and sagittal planes from reformatted MRI spine. Volumes of VB, IVD and nucleus pulposus (NP) were evaluated on volumetric images. One-way ANOVA with Bonferroni correction and Pearson correlation tests were used.

**Results and Discussion**

There was significant difference in wedge angle and height ratio of VB and IVD between AIS and controls( $P<0.001$ ). In severe-AIS, the position of NP was significantly shifted to the convexity when compared with non-severe AIS ( $P<0.001$ ) and controls ( $P<0.001$ ) (Figure 1A and 1B). Whereas, the volume of IVD and NP in severe-AIS was found to be significantly smaller( $P<0.001$ ). Additionally, Cobb angle was significantly correlated with wedge angles and height ratios, and inversely correlated with the volume of NP.

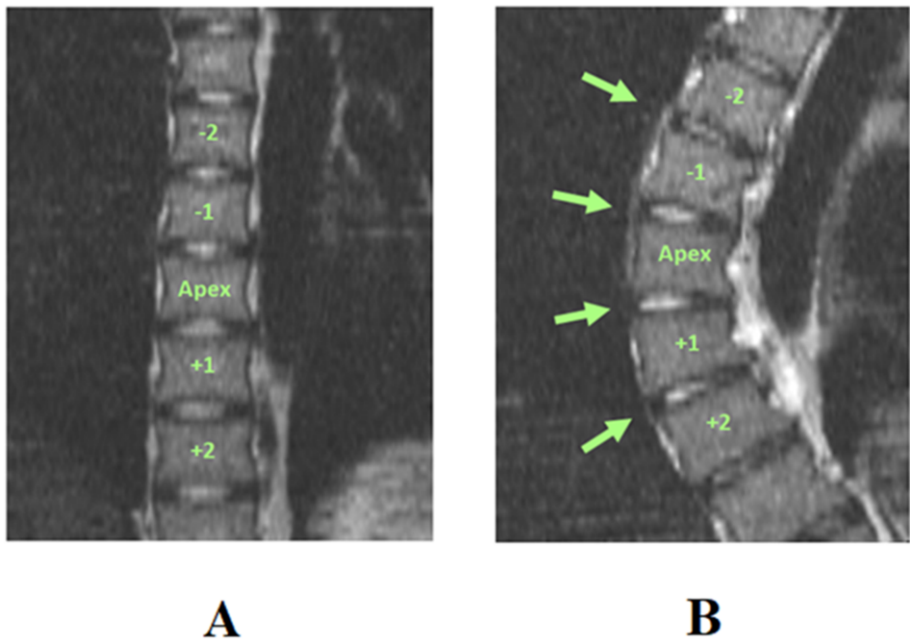


Figure 1. The morphological change of intervertebral discs and vertebral bodies in control (Figure 1A) and severe-AIS (Figure 1B). T2 coronal MR image shows the nucleus pulposus is central in location in control but shifted to the convexity (arrows) in AIS with a severe curve.

## Conclusions and Significance

On top of coronal wedging of VB and IVD, there was significantly reduced volume of IVD and NP in severe-AIS patients with a severe curvature, despite T2 signal of IVD was preserved. The current findings indicate that early mechanical effects on the discs and vertebrae in adolescent scoliotic spine is evident on quantitative imaging. Importantly, these patients may be vulnerable to disc degeneration if no operative treatment is prescribed.

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# A purpose-design computational method for estimation of plane of maximum curvature in Adolescent Idiopathic Scoliosis

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**Abstract:** Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional (3D) deformity, and the plane of maximum curvature (PMC) is proposed to reflect these clinical features, which refers to a vertical plane presenting the maximum projected spinal curvature and its parameters include the PMC Cobb and orientation (angle between PMC and sagittal planes). This study aimed to develop a computational method (CM) for PMC estimation. Twenty-nine patients with AIS and computed tomography (CT) images were recruited. For CT, PMC was determined by rotating a vertical plane about its vertical axis with 5° increment until the maximum Cobb angle was measured. For CM, PMC was estimated via identifying the eight points (the corner points of the superior and inferior endplates of the upper and lower end-vertebrae respectively) in the coronal and lateral CT images. Two experienced raters repeated the PMC estimation three times with one-week interval. The intra-class correlation coefficient (ICC) and Bland-Altman method were used for statistical analysis. Twenty-seven right thoracic curves (RTs) (mean Cobb: 46.1°±12.4°) and 23 left thoracolumbar/lumbar (LTLs/LLs) (mean Cobb: 30.6°±11.1°) were analysed. The intra- and inter-rater ICC values were >0.91 and 0.84 in RTs and LTLs/LLs, respectively. The PMCs obtained from the CM and CT were showed good agreement was also observed between the PMCs obtained from the two methods according to ICC (>0.90) and Bland-Altman method assessments. This purpose-design computational method could provide reliable and valid estimation of PMCs for AIS, which has potential to be used as an alternative for 3D assessment.

**Keywords:** Adolescent Idiopathic Scoliosis; Three-dimensional Assessment; Computational Method; Plane of Maximum Curvature

## Introduction

Adolescent idiopathic scoliosis (AIS) is a complicated three-dimensional (3D) deformity of spine.[1] The Cobb angle measured from the coronal radiograph is the gold standard for the clinical assessment of scoliosis,[2] but it may underestimate the severity of spinal curvature and also cannot fully reflect the pattern of spinal curve.[3,4] The plane of maximum curvature (PMC) was considered as a promising descriptor for the 3D assessment of scoliosis[5] and has been increasingly valuable in orthopedic operation of spine.[6] PMC is defined as a vertical plane that positions between the sagittal and coronal planes, and presents the maximum spinal curvature.[1] Its parameters include

the maximum Cobb angle in PMC (PMC-Cobb) and orientation of PMC (PMC-orientation, the angle between the PMC and the sagittal plane)[7]. PMC could be estimated through rotating a vertical plane, where a spinal curve is projected onto, until the maximum Cobb angle is found. However, 3D reconstruction model of scoliotic spine was required.[3,8,9] The computed tomography (CT), which is recognized as valid 3D assessment of scoliosis, can also be used to obtain the PMC. However, it was commonly applied to severe cases, not for routine clinical application to mild or moderate cases because of high radiation exposure. Therefore, this study aimed to develop a more user-friendly computational method (CM) to estimate the PMC basing on the coronal and sagittal images, and to verify the results with CT.

## Methods

### Subjects

Twenty-nine were selected from the database of a local hospital using the criteria: diagnosed with AIS; age between 10-24; coronal-Cobb at 10°-80°; and with CT images of the whole spine. Those who had prior surgical treatment or other diseases affecting the spinal profile were excluded. Human subject ethical approval was granted from the authors' Institutional Review Board.

### PMC estimation using CM

The CM was based on the global axis system (x, y, z) of the human body with the origin at the center of the superior endplate of the 1<sup>st</sup> sacral vertebra.[10] It assessed the spinal curve by calculating the angle ( $\beta$ ) formed by the intersection lines of a vertical plane and the superior endplate of the upper-end vertebra and the inferior endplate of the lower-end vertebrae of a specific spinal curve (Figure 1). The Cobb angles ( $\beta$ ) in different vertical planes were calculated based on the 3D coordinates of the 8 points at the superior endplate of the upper end vertebra and the inferior endplate of the lower end vertebra in the sagittal and coronal planes using the formula as below, and the maximum Cobb angle ( $\beta_{\max}$ ) could be then determined among the calculated Cobb angles ( $\beta$ ).

$$\beta = \arccos \frac{(2aceg + adeh + bcfg) + (adeh - bcfg)\cos 2\theta + (adgf + bceh)\sin 2\theta}{\sqrt{(2a^2c^2 + a^2d^2 + b^2c^2) + (a^2d^2 - b^2c^2)\cos 2\theta + 2adbc\sin 2\theta} \sqrt{(2e^2g^2 + e^2h^2 + f^2g^2) + (e^2h^2 - f^2g^2)\cos 2\theta + 2ehgf\sin 2\theta}}$$

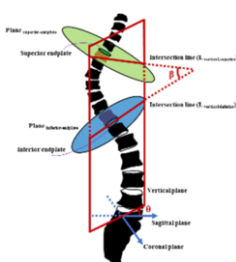


Figure 1. the superior endplate of the upper-end vertebra and the inferior endplate of the lower-end vertebra of a specific spinal curve are assumed to be on the planes that can be extended outward named Plane<sub>superior-endplate</sub> and Plane<sub>inferior-endplate</sub>, respectively to ensure the intersections between the 3 planes. A vertical plane intersects with Plane<sub>superior-endplate</sub> and Plane<sub>inferior-endplate</sub> at L<sub>vertical-superior</sub> and L<sub>vertical-inferior</sub> respectively; and the angle ( $\beta$ ) formed by the intersection lines is the Cobb angle of the spinal curve in that vertical plane. The orientation of that vertical plane is the angle between that vertical plane and the sagittal plane ( $\theta$ ).

### *PMC estimation using CT*

With all the CT images visualized three-dimensionally using an open-source image processing software named 3DSlicer (version 4.8.1, 3DSlicer Platform: [www.slicer.org](http://www.slicer.org)), a plane, where the spine was projected onto, was rotated 90° axially from the sagittal plane to the coronal plane with 5° increments) the Cobb angle in each rotated plane was measured. The maximum Cobb angle could be then identified, and the rotated plane presenting the maximum Cobb angle was recorded as the PMC.

### *Data collection*

Two experienced raters participated in data collection. Based on the same set of the coronal and sagittal CT images of the spine, each rater used the CM to estimate the PMC 3 times with one-week interval. One of the raters measured the PMC 3 times using the CT constrained and unconstrained Cobb methods based on the same set of rotated CT images using the same protocol.

### *Statistical analysis*

Statistical analyses were performed in SPSS (version 21, IBM, USA) with a significant level of 0.05. The intra-class correlation coefficient (ICC) with 95% confidence interval was used for the reliability analysis of CM. The strength of reliability was evaluated using the criteria: very reliable (ICC=0.8-1.0), moderately reliable (ICC=0.60-0.79) and questionably reliable (ICC<0.60).[11] The validity of the PMC acquired using the CM was analysed using the ICC, Pearson correlation coefficient (r), and Bland-Altman method. The linear regression analysis was also performed with the correlation coefficient: 0.75-1.00 indicating very good to excellent, 0.50-0.75 indicating moderate to good and 0.25-0.50 indicating poor correlation.[12]

## **Results and Discussion**

A total of 50 curves were eligible for this study, including 27 RTs (mean coronal-Cobb: 46.1°±12.4° with a range of 26.2°-71.1°) and 23 LLs (mean coronal-Cobb: 30.6°±11.1° with a range of 16.4°-54.2°).

### *Reliability of the CM in the PMC estimation*

As shown in Tables 1 & 2, the intra- and inter-rater ICC values were from 0.91- 0.98 and 0.84-0.91, respectively, being similar to those for the coronal-Cobb reported previously.[13,14] This demonstrated very good reliability of CM in PMC estimation for the RTs and LLs.



Table 1. Intra-rater reliability of the CM in PMC estimation for different curve types

PMC Parameter	ICC	
	Rater 1	Rater 2
<u>RTs</u>		
PMC-Cobb	0.952	0.983
PMC-Orientation	0.912	0.949
<u>LLs</u>		
PMC-Cobb	0.965	0.977
PMC-Orientation	0.958	0.982

Table 2. Inter-rater reliability of the CM between the two raters in PMC estimation for different curve types

PMC Parameter	ICC
<u>RTs</u>	
PMC-Cobb	0.905
PMC-Orientation	0.912
<u>LLs</u>	
PMC-Cobb	0.877
PMC-Orientation	0.839

Validity of the CM in PMC estimation

As shown in Table 3, high ICC values (0.91 to 0.97 with mean: 0.94±0.02) were found between PMCs (PMC-Cobb, PMC-orientation) obtained from the CM and CT constrained and unconstrained Cobb methods for the both RTs and LLs. Moreover, according to the Bland-Altman method assessment (Figure 2), all the PMCs (PMC-Cobb, PMC-orientation) almost distributed around the central lines and the mean differences were within (2.9°, 3.1°) for RTs, and (5.1°, 4.3°) for LLs, being smaller or close to the clinical accepted error (5°).<sup>15</sup> These results suggested good agreements between the PMCs obtained from the CM and CT.

Table 3. The comparison of PMC estimation using CM and CT for different curve types.

PMC parameter	PMC		ICC between CM and CT
	(mean ± standard deviation) (°)		
	CM	CT	
<u>RTs</u>			
PMC-Cobb	48.0±11.4	50.8±12.7	0.968
PMC-orientation	-74.8±9.1	-72.7±8.9	0.909
<u>LLs</u>			
PMC-Cobb	39.8±9.9	44.6±9.4	0.948
PMC-orientation	-234.8±16.1	-232.4±17.1	0.958

The PMC has been used in the 3D assessment[8,16] and 3D classification[17] of scoliosis as well as in 3D correction evaluation of surgical[18] and orthotic[19] treatment. Since providing information about both the actual magnitude of a curve and the degree of a curve being shift towards the coronal plane, the PMC would be superior to other clinical indices, such as the coronal Cobb and apical vertebral rotation, in the description of 3D deformities. As pointed out by Labelle, et al.[20], a curve type proposed by a conventional method (Lenke classification system) could be further split into different curve sub-types based on the PMC (the best fit plane / the plane passing through the end-apical-end vertebrae). Different curve sub-types may require different surgical strategies or different orthosis designs; thus, it should be considered when making surgical strategy or designing spinal orthosis. These have revealed the importance of PMC in the clinical assessment and management of scoliosis.

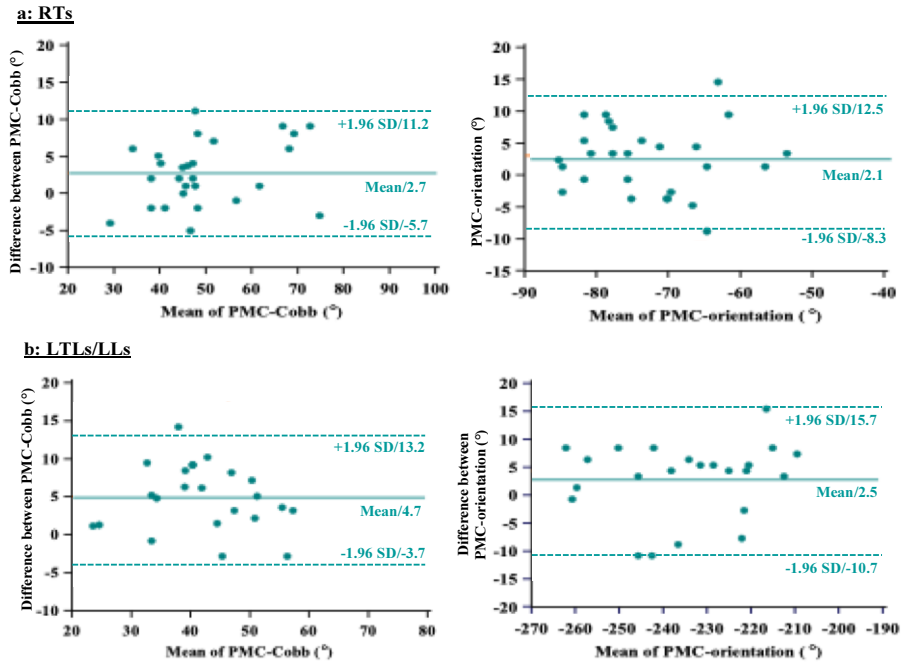


Figure 2. Bland-Altman plot assessing the agreement of PMCs obtained from the CM and CT constrained and unconstrained Cobb methods for the RTs and LLs (Mean = (CT+CM)/2; Difference = CT-CM).

## Conclusion and Significance

This study developed a computational method for PMC estimation from the coronal and sagittal images with further validation by CT. The results found that the PMC measurements (PMC-Cobb, PMC-orientation) obtained from the computational method were very reliable and had a good agreement in comparison with the CT constrained and unconstrained Cobb methods. These results suggested that the computational method would have the potential to be applied as a useful tool for the 3D assessment of AIS and enhancement of AIS management.

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# Does improved radiographic alignment truly enhance dynamic functional balance?

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**Abstract:** Prospective, concurrent-cohort study. To establish the relationship between radiographic alignment parameters and functional CoE measurements at one week before and at three months after realignment surgery in ADS patients. Adult degenerative scoliosis (ADS) represents a significant healthcare burden with exceedingly high and increasing prevalence, particularly among the elderly. Radiographic alignment measures and patient-reported outcomes currently serve as the standard means to assess spinal alignment, deformity, and stability. Neurological examinations have served as qualitative measures for indicating muscle strength, motor deficits, and gait abnormalities. Three-Dimensional motion analysis is increasingly being used to identify and measure gait and balance instability. Recently, techniques have been established to quantify balance characteristics described by Dubousset as the “cone of economy” (CoE). The relationship between radiographic alignment parameters and CoE balance measures of ADS patients before and after realignment surgery is currently unknown. 29 ADS patients treated with realignment surgery. Patients were evaluated at one week before realignment surgery and at their three-month follow-up examination. During each evaluation, patients completed self-reported outcomes (visual analog scales for pain, Oswestry Disability Index, SRS22r) and a functional balance test. Mean changes in dependent measures from before to after surgery were compared using paired t-tests. Pearson correlations were used to test for significant correlations between changes in radiographic and CoE measures. Significant improvements were found for all patient-reported outcomes, in several radiographic measures, and in CoE measures. Improvements of scoliosis Cobb angle, coronal pelvic tilt, lumbar lordosis, and thoracic kyphosis showed significant correlations with CoE sway and total distance measures at both the center of mass and center of the head. Improved radiographic alignment measures significantly correlated with improved CoE balance measures among ADS patients treated with realignment surgery at their three-month follow-up. These findings indicate that functional balance evaluations when used in conjunction with radiographic measurements, may provide a more robust and improved patient-specific sensitivity for postoperative assessments. CoE balance may represent a new measure of added value for surgical intervention of ADS.

**Keywords:** Adult degenerative scoliosis, cone of economy, balance, radiographic alignment

## Introduction

In the diagnosis and treatment of adult spinal deformities, static radiographic measurements in the sagittal and coronal anatomical planes serve as the gold standard for assessment of spinal alignment and deformity.[1] In addition to the radiographic

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evaluation, neurological examinations are routinely used for evaluating muscle strength, motor coordination, and functional abilities like gait.[1,2] Despite the fact that radiographic alignment parameters have been shown to have strong correlations with patient-reported outcome measures (PROMs) for pain, and disability, there is a paucity of quantifiable indicators which directly measure a patient's individual functional abilities.[3,4] Dynamic balance is the product of a delicately coordinated relationship between sensorineural, nervous, and musculoskeletal systems to maintain the center-of-mass (CoM) within a base of support with minimal postural sway and energy expenditure.[5,6] The notion of a "Cone of Economy" (CoE) was coined by Jean Dubousset in reference to a stable region of standing posture within which the least energy is expended in order to maintain an upright posture and a horizontal gaze.[7] Deviation outside of one's CoE presents a challenge to the efficiency and sustainability of balance mechanisms.[7] Since its inception, the CoE has consistently been referenced as a guiding principle for spinal realignment targets.[1,3] Focus has however, been predominantly from a radiographic perspective of the CoE, with much less attention directed towards more physical measures like dynamic balance or gait evaluations. This may partly be due to the lack of immediately available resources to measure physical function in a typical clinical setting. With the persistence of challenging postoperative complication like proximal junctional kyphosis, rising treatment costs, and pressures for improved value-of-care metrics, there is a need for improved diagnostic and assessment techniques to allow realignment surgery to adequately address these demands.[8,9]

The use of three-dimensional (3D) motion capture analysis has seen consistent, although limited, interest as a clinical tool for evaluation of functional abilities and balance. [5,10-13] A previous study by Haddas et al. established a standardized protocol for quantifying CoE balance and demonstrated significant differences in dynamic balance of adult degenerative scoliosis (ADS) patients compared to healthy controls.[5] While these techniques are still relatively early in development and adoption among spine surgeons and spine clinics, it appears to be a viable consideration for adding additional insight and value to diagnostic and treatment outcome metrics.

To date, no study has made a direct relation between ADS patient's radiographic changes to functional CoE balance changes using kinematic motion capture data. The purpose of this study was to correlate radiographic alignment parameters to functional CoE balance measures at one week before and at three months after realignment surgery in ADS patients. We sought to answer the question: "Does an adequately aligned spine give ADS patients a better chance of functioning within their CoE?"

## **Methods**

A total of 29 ADS patients were included in this study (26 females, Age:  $56.6 \pm 15.8$  years; Height:  $1.59 \pm 0.1$ m; Weight:  $64.0 \pm 14.4$ kg; Body-Mass Index (BMI):  $25.3 \pm 5.4$ kg/m<sup>2</sup>). Each patient underwent full-length, head-to-toe, micro-dose x-rays to generate coronal and sagittal views of the spine, pelvis, and lower extremities at both Pre and Post evaluations. Radiographic parameters were measured using a sterEOS system (EOS Imaging, Paris, FR) by a single trained imaging technician. Measurements included pelvic incidence (PI), sacral slope (SS), sagittal and coronal pelvic tilt (PTs and PTc respectively), thoracic kyphosis (TK, T1-12), lumbar lordosis (LL, L1-S1), sagittal vertical axis (SVA), center of acoustic meati (CAM), spinosacral angle (SSA), T1 sagittal tilt (T1A), T9 sagittal tilt (T9A), knee flexion angle (KF), and coronal primary

scoliotic Cobb angle (SC), coronal vertical axis (CVA), and PI-LL mismatch (PILLm) [3, 14]. At each evaluation, patients first completed questionnaires including back and leg Visual Analog Scales for pain (VAS), Oswestry Disability Index (ODI), and Scoliosis Research Society 22r (SRS22r). Prior to balance testing, subjects were fitted with a full-body reflective marker set normally used in our lab for functional evaluations.[5,10,15] Each patient performed a series of three functional balance tests at each evaluation. In short, the test protocol is similar to a 60 second Romberg's test with eyes open.[5,16] The average of the three trials was calculated and used for further analysis. Balance was measured using a protocol previously developed by our lab which quantifies the CoE as a combination of range-of-sway (RoS) and total sway distance of the center-of-mass (CoM) and the center-of-head (CoH).[5] Primary CoE measures for this study included RoS and total sway distance of the CoM and CoH in the sagittal, coronal, and axial planes. 3D kinematic data was recorded at 100Hz using a ten-camera Vicon motion-tracking system and processed in Nexus 2.7 software (Vicon, Oxford, UK). Kinematic data was low-pass filtered with a 4<sup>th</sup>-order Butterworth filter at a 4Hz cutoff frequency. CoE parameters were calculated using a custom Matlab program (The Math Works, Natick, MA, USA). Paired t-tests were used to test for significant changes in Pre and Post data sets for PROMs, radiographic measures, and CoE measures. Pearson's product correlations were used to identify significant relationships between Pre to Post changes in radiographic alignment and CoE balance measures. Statistical significance was set at an alpha of  $p < 0.05$ . Statistical analyses were performed using Excel (Microsoft, Redmond, WA, USA) and SPSS (IBM, Armonk, NY, USA).

## Results and Discussion

### *Effects of Surgical Treatment*

Significant improvements were found in both VAS low back pain ( $p=0.043$ ), VAS leg pain ( $p=0.033$ ). A significant improvement was found in ODI total score ( $p=0.003$ ) with an average reduction of 9.4 points which is close to previously published changes for an early (3 months) minimum clinically-important difference (MCID) for ODI.[17,18] Significant changes in SRS22r function ( $p=0.003$ ), self-image ( $p=0.006$ ), mental health ( $p=0.004$ ), and total ( $p=0.001$ ) from Pre to Post were also observed. The SRS22r total improvement from Pre to Post was 0.4 which corresponds to previously published MICD thresholds for clinically relevant improvements in function.[19] As expected for surgical realignment of ADS the primary SC angle show significant reduction ( $p < 0.001$ ). Significant improvements in the sagittal plane included TK ( $p=0.017$ ) and SSA ( $p=0.032$ ). Notable improvements were also seen in SS and LL however these did not reach statistical significance ( $p < 0.100$ ). Significant reductions (improvements) in all CoE measures were found: CoE dimensions and CoM and CoH RoS.

### *Correlation of Changes Between Radiographic Alignment and CoE Balance*

Significant correlations were found only for axial RoS. For the COM, axial RoS significantly correlated with CVA ( $r=0.637$ ,  $p < 0.001$ ). For COH, axial RoS significantly correlated with CVA ( $r=0.762$ ,  $p < 0.001$ ), SC ( $r=0.375$ ,  $p=0.045$ ), and T1A ( $r=-0.413$ ,  $p=0.026$ ). Notable relationships were also found between CoH axial RoS and SVA, CAM, and T9A however these did not reach significance ( $p < 0.100$ ).

In a previous study conducted by our lab, CoE balance measures were collected for ten symptomatic ADS patients and for ten healthy adults and found significantly greater RoS and total sway distance among the ADS group.[5] Compared to the previous study, the current ADS group is slightly older (56.6yr vs 48.5yr) and has a slightly lower average Cobb angle (37° vs 42°). The ADS patients from the current study exhibited markedly worse CoE balance at the Pre evaluation, and while they did show significant improvements, were actually not much better at Post than the previous studies symptomatic condition. Similarly, the Post CoE measures of the present study are still relatively poor compared to the data from the previous studies healthy control group indicating that there may still be deficits in dynamic balance which may be related to recovery.

The results of our correlations found that changes in RoS were correlated to only a select few radiographic measures and only in the axial direction. Significant correlations in the coronal plane included CVA and SC for axial RoS. CVA is commonly used as an indicator of global alignment in the coronal plane.[1] The coupling of CVA with SC provides details of both the coronal alignment balance (lateral shift from the neutral center) and degree of curvature resulting from the scoliosis.[2] These correlations suggest that strong coronal re-centering and realignment should result in greater axial stability and better posture. The underlying mechanism of this relationship is however not clear. Coronal realignment may provide back muscles with improved symmetry which in turn could improve axial stability, however other factors like surgical invasiveness, healing, physical rehabilitation, and changes in activity level likely have concurrent effects as well. The lack of correlation of coronal measures to coronal RoS suggests that additional details such as lower limb recruitment and compensation may be providing equal or greater contributions to coronal RoS. In the sagittal plane, the only radiographic measure that showed a significant correlation was T1A to CoH axial RoS. Although not significant, SVA and CAM, which describe similar alignment characteristics to T1A, did show notable trends as well. Again, the lack of substantial correlations between sagittal measurements and sagittal RoS suggests that additional considerations may be needed to better describe the key drivers of sagittal RoS.

Lack of significance in correlations in conjunction with significant improvements in both radiographic alignment and COE balance emphasizes the importance of utilizing both evaluation techniques for the optimal evaluation of overall balance. This raises the question of whether improved dynamic balance should be expected from an otherwise successful realignment. Perhaps improved CoE balance is driven as much by back and lower limb muscles and coordination as the alignment of the spine itself. Clearly, CoE balance is driven by more than static, standing radiographic alignment alone. The overall indication of how well balanced a spine is should be thought of as not only what the realignment “gives the patient” but “what they can do with it” as well. Consideration of challenges in preventing and managing postoperative complications among ADS patients provides useful insight into this notion. Glassman et. al. studied a wide array of risk factors associated with proximal junction kyphosis (PJK) and ultimately concluded that key aspects of the complication likely lie outside the realm of purely mechanical factors.[8] Growing attention on complications like PJK, muscular atrophy or fatty infiltration, neuromuscular comorbidities, and frailty within the scope of treatment of ADS all emphasize the importance of expanding the scope of what drives true balance.[8,20,21] In each of these, quantified CoE balance may help serve as a central, patient-specific indication and link to help better describe their interactions. The presence of improvements in both suggest that CoE balance measure provide new insight into the

degree of preoperative disability and postoperative outcome beyond what current techniques can provide. Additionally, the significant reduction in SRS22r function score in the presence of significantly improved CoE balance measures raises the question whether these two measures are actually measuring two different, possibly independent factors contributing to balance or functional ability. It is difficult to discern whether these findings are due to a limited sample size or to a lack of more detailed classification of deformity.

The greater preoperative axial RoS is likely a direct result of the scoliotic curve adding additional axial flexibility and mobility. Realigning the scoliotic vertebra into the central coronal axis allows for the bulk of the axial RoS to be more naturally managed by the kyphotic and lordotic curves in the sagittal plane. Reduction in axial sway may have a profound impact on reducing effort to maintain a horizontal gaze which has been shown to be a key driver in the establishment of global spinal alignment.[6,22] The absolute values of axial sway are, however, relatively small in comparison to coronal and sagittal sway, so it may be difficult to elucidate and explain effects of axial sway independently. Additional factors such as lower limb muscle strength, motor coordination, and compensatory mechanisms due to pain may also be contributors to differences in axial RoS. The results of this study suggest that there is important information to be gained from each evaluation technique and that efforts should be made to utilize both for optimal assessment of preoperative disability and surgical outcomes.

It is important to note several limitations of this study. The representative patient population included in this study exhibited high inter-subject variability which is, in part, due to a relatively limited sample size. The follow-up timing of three months may also be relatively early within the full recovery period which may not be indicative of long-term outcomes. We believe nonetheless that both short- and long-term details regarding patient recovery are important for better understanding the complete scope of recovery and in the reestablishment of functional abilities. There is inherent bias in radiographic measurements, however this is not unique to this study and we attempted to control this by using a single technician for radiographic evaluations. Limitations associated with the motion capture system include variance in marker placement, marker shifting due to skin movement, tracking errors, approximation errors in anthropomorphic model fitting, and data processing errors due to filtering.

## **Conclusion and Significance**

The goal of this study was to determine whether improvements in radiographic alignment yield proportional corresponding improvements in dynamic functional balance. Significant relationships were identified between radiographic realignment and improved functional balance, however not across all commonly used static radiographic alignment measures and not in all CoE balance measures. These findings, in the presence of significant individual improvements in both radiographic alignment and CoE balance measures, indicate that the combined use of both provides a better assessment of overall spinal balance. Evaluation of balance using CoE measures can serve as a simple, more reliable method for quantifying functional balance compared to more complex techniques involving gait analysis.

This study emphasizes the importance of appreciating the scope of effects that spinal deformities inflict on an individual and on how surgical intervention can impact their daily life. The key findings of this study indicate that more detailed information



regarding dynamic compensation within the current CoE balance measures may be needed to provide better sensitivity to relationships between planar alignment and functional balance. Based on our findings, we recommend that spine care practitioners include CoE balance measures as a standard part of preoperative and postoperative evaluations in order to better understand appropriate treatment options and to objectively document the effectiveness of their interventions.

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# How different the scoliotic curves are?

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**Abstract:** The pathomechanism of spinal deformity development in adolescent idiopathic scoliosis (AIS) has been related to the sagittal curvature of the spine. It is not known how the variations in the sagittal profile relates to the coronal deformity patterns in AIS. A total of 70 Lenke 1 and 50 Lenke 5 AIS patients were included retrospectively. A finite element (FE) model was developed for each spine where the sagittal spinal curvatures were modeled as 2D S shaped elastic rods. Transverse plane deformation patterns of these rods under physiological loading were determined and clustered based on their similarities. The patients' characteristics, including the Lenke type, and the spinal measurements in these deformation pattern clusters were statistically compared. Three different axial deformation patterns were determined from the FE simulations of the 120 sagittal curves. Two axial groups were looped shaped in opposing directions (Group I and III) and one was lemniscate shaped (Group II). 94% of the patients in Groups I and II were Lenke 1 and 100% of Group III was Lenke 5. The position of the sagittal inflection point moved downward from Group I-III resulting in significantly different ratio of the arc lengths above and below the sagittal inflection points for Groups I, II and III ( $0.49\pm0.59$ ,  $1.15\pm0.44$ , and  $3.22\pm1.8$ ). A classification of idiopathic scoliosis, based on the biomechanics of S-shaped flexible rods deformation could distinguish between different coronal curve types. The geometrical parameters of the sagittal profiles in the axial deformation pattern groups were significantly different.

**Keywords:** Adolescent Idiopathic scoliosis; Sagittal profile; Elastic rod; Finite element model

## Introduction

As the search for adolescent idiopathic scoliosis (AIS) etiology and pathogenesis continues, the biomechanical factors are becoming more recognized.[1-4] Among these factors, the role of the sagittal curvature of the spine in induction of scoliosis has been proposed.[1,2,5] Yet, the classification systems of AIS, which plays an important role in clinical management of the disease,[6,7] do not account for the sagittal curve patterns. Moreover, since all knowledge on scoliosis is based on the patients with deformed spines, it is not known if variations in sagittal profile precede the coronal deformity, or are caused by it. A more fundamental, biomechanical approach may get us closer to unraveling this dilemma.

Using mechanisms of deformation in elastic rods of varying S-shaped curves, it was shown previously that the position of the inflection point and the curvatures of the rod above and below the inflection point determine the rod's deformation patterns in the horizontal plane.[2,8,9] In this study we aimed to determine if the deformation patterns of S shaped rods, with the geometry of the sagittal curves of different Lenke types, produce transverse projection patterns that match the transverse plane

projection of the spine in the AIS subtypes. Secondly, we aimed to determine if the sagittal profiles that deform in the same manner in the transverse plane, also belong to the same coronal deformity of the most common AIS subtypes, i.e. Lenke 1 and Lenke 5 scoliosis.[10]

## Methods

### *Patient population*

120 AIS patients (70 Lenke 1 and 50 Lenke 5) were included. All patients had biplanar standing stereoradiographs and bending films to determine the Lenke types. All aspects of the study procedures were approved by the institutional review board.

### *Image processing*

3D reconstructions of the spinal radiographs were created in SterEOS 2D/3D (EOS imaging, Paris, France).[11] The 3D models then were used to extract the vertebral centroids and create the 3D centerline of the spine[12] and isotropically normalized for spinal heights.[12] Spinal and pelvic parameters were calculated using this 3D models.[13]

### *Finite element simulation of the sagittal curvatures*

The sagittal curvature of the spine was used to develop a 2D reduced order finite element model (FEM) of the spine[2] with following parameters: homogeneous, isotropic, slender elastic rod (Young modulus=1000Pa and Poisson ratio=0.3, radius=1mm and length=1m) and loaded by vertical loading (gravity) at each vertebral level and a small torsional moment ( $+1e-4$  N.mm) along the Z-axis.[2]

### *Axial classification of the curves*

The projection of the deformed rods on the transverse plane was determined. The 2D coordinates of the 17 vertebrae on the transverse plane formed an array that was used in a C-means fuzzy classification to determine the total number of different axial projection patterns based on the silhouette values. [14,15] The average sagittal curve of the normalized spine in each of the axial cluster groups was determined. The Lenke types of the patients in each of the axial clusters were determined. The spinal and pelvic parameters were compared between the axial projection pattern groups.

## Results and Discussion

### *Rod deformation resulted from the FEM simulation:*

Silhouette analysis of the axial projection patterns of the 120 deformed S shaped rods determined three axial clusters (Figure 1): Group I (n=39): loop shaped axial projection (projected on the second and third quadrant), Group II (n=35): lemniscate

shaped axial projections, and Group III (n=46): loop shaped, projected mainly on the first and fourth quadrant (Figure 1).

Spinal and pelvic parameters and Lenke classification

Table 1 summarizes the spinal and pelvic measurements. All the patients in Group I were Lenke 1A and B, majority of patients in Group II were Lenke 1 B and C (82%), and all the patients in Group III were Lenke 5 B and C. The average of the sagittal, frontal, and axial spinal centerline are shown in figure 2. Group I has one thoracic curve (one 3D curve), Group II has thoracic and lumbar curves (two 3D curves) and Group III has a single lumbar curve (one 3D curve) (Figure 2). The transverse view showed loop shaped projection for Group I and III (in opposite directions) and a lemniscate shape projection for Group II (Figure 2).

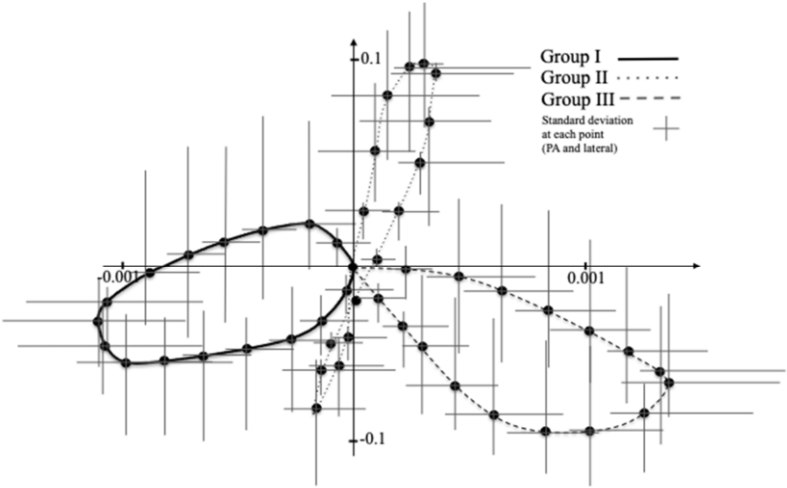


Figure 1. The three deformation patterns resulted from the finite element analysis. Group I: a loop shaped axial projection (no corssing) deformed to the left. Group II: a lemniscate axial projection. Group III: a loop shaped axial projection deformed to the right. The X-, Y-axis shows the deformed shap of the normalized (unitless) rods.

Table 1. The spinal and pelvic parameters in the two clusters of the Lenke 1 (Group I and Group II) and Lenke 5. **NS: not significant.**

Axial curve patterns	Thoracic Cobb (°)	Lumbar Cobb (°)	T5-T12 Kyphosis (°)	L1/S1 Lordosis (°)	Pelvic incidence (°)	Sacral slope (°)	Main curve AVR (°)
Group I	62.4±9.3	38.2± 11.3	14.7±9.7	54.5±12.1	49.1±10.2	43.3± 11.6	13.8±6.4
Group II	56.6± 10.1	40.9±9.5	20.6±12.5	55.3±14.2	52.6±9.8	44.5± 10	16.2±8.8
Group III	25.7 ±4.2	43.5± 12.5	22.6±15.7	51.8±10.2	55.5±9.3	40.8± 12.6	25.2±8.5
P value	0.035	NS	0.041	NS	NS	NS	0.038

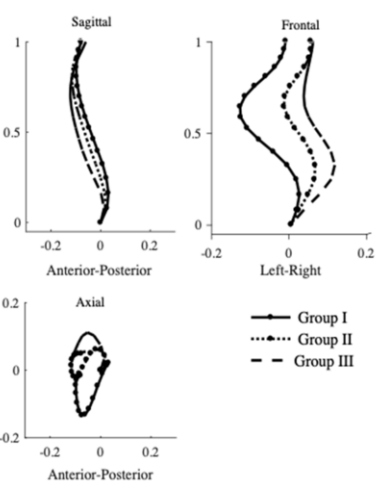


Figure 2. The Frontal, Sagittal, and Axial spinal centerlines of the three axial clusters (Groups I-III).

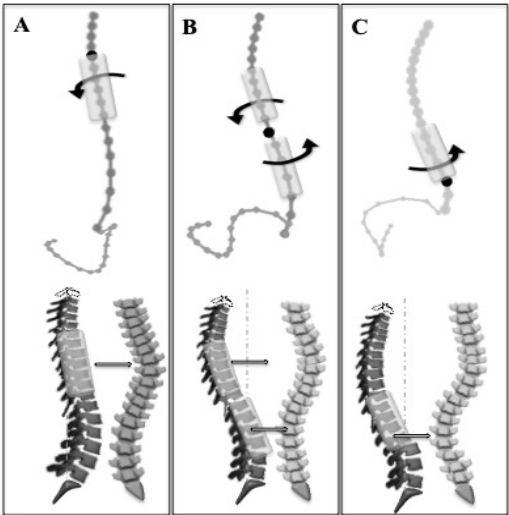


Figure 3. Schematics of the sagittal curve and the corresponding axial and frontal curves in Groups A) I, B) II, C) III.

We showed that the patterns of axial projection of the spine in Lenke 1 and 5 AIS patients relates to the axial projection of S shaped elastic rods that have the same curvature as the sagittal profiles in this patient group. We further showed the number of 3D curves as shown in the axial projections (loop versus lemniscate) relates to the coronal deformity of the spine distinguishing patients with one long coronal curve (Groups I and III) from patients with two 3D curves and twisted S shaped coronal deformity (Group II).

The mechanics of elastic rods were used to explain scoliotic curve development in AIS from a mechanical standpoint.[2,8] It was shown that the shape of the sagittal curvature of the spine impacts its mechanical loading which, in a fast growing spine may cause instability and lead to 3D deformity development.[8,9] The geometry of the S shaped curve, such as the curvature and inclination of the curve, among other factors, determines the magnitude and direction of the moments that deform the elastic rod in 3D (Figure 3).[8,9] The current analyses showed in patients with a long lordotic sagittal curve (Group I), the coronal curve is more dominant in the sections of the spine with a kyphotic curve and the adjacent section without any sagittal curvature-i.e., transition section between the kyphotic and lordotic sections of the spine (Figure 3A). On the other hand, in Group III, patients with a long kyphotic sagittal curve, the largest coronal curve occurred in the shorter lordotic section along with the adjacent section with zero sagittal curvature (Figure 3C). As the arc length of the kyphotic and lordotic sections are close in Group II, both kyphotic and lordotic sections deflected in 3D resulting in two opposing 3D curves (Figure 3B). The impact of the sagittal curvatures on the stiffness, range of motion, and muscular forces in different sections of the spine prior to onset of scoliosis and how it dictates the development of the structural coronal curves merits further investigations.

## Conclusion and Significance

As the scoliosis impacts the spinal alignment in the three anatomical planes, understanding the biomechanics of the curve development and the connection between the planar deformities of the spine is key for systematic classification of the patients both for etiological studies and treatment of the patients. The presented work here showed the impact of the sagittal curves on the deformation patterns of the spine identifying subtypes within the Lenke types.

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# Anterior lengthening in scoliosis occurs only in the disc and is similar in different types of scoliosis

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**Abstract:** Relative anterior spinal overgrowth (RASO) was proposed as a generalized growth disturbance and a potential initiator of adolescent idiopathic scoliosis (AIS). However, anterior lengthening was also observed in neuromuscular (NM) scoliosis, was shown to be restricted to the apical areas and to be located in the intervertebral discs, not in the bone. In this study the goal was to determine if other scoliotic curves of known origin exhibit the similar mechanism of anterior lengthening without changes in the vertebral body. Therefore CT-scans of 18 patients in whom a short segment congenital malformation had led to a long thoracic compensatory curve without bony abnormality were included. Of each vertebral body and intervertebral disc in the compensatory curve, the anterior and posterior length was measured on CT-scans in the exact mid-sagittal plane, corrected for deformity in all three planes. The total AP% of the compensatory curve in congenital scoliosis showed a lordosis (+1.8%) that differed from the kyphosis in non-scoliotic controls (-3.0%;  $p < 0.001$ ), and was comparable to AIS (+1.2%) and NM scoliosis (+0.5%). This anterior lengthening was not located in the bone; the vertebral body AP% showed a kyphosis (-3.2%), similar to non-scoliotic controls (-3.4%), as well as AIS (-2.5%) and NM scoliosis (-4.5%;  $p = 1.000$ ). However, the disc AP% showed a lordosis (+24.3%), which sharply contrasts to the kyphotic discs of controls (-1.5%;  $p < 0.001$ ), but was similar to AIS (+17.5%) and NM scoliosis (+20.5%). The results demonstrate that anterior lengthening is part of the three-dimensional deformity in different types of scoliosis and is exclusively located in the intervertebral discs. The bony vertebral bodies maintain their kyphotic shape, which indicates that there is no active bony overgrowth. Anterior lengthening appears to be a passive result of any scoliotic deformity, rather than being related to the specific cause of AIS.

**Keywords:** Idiopathic scoliosis, congenital scoliosis, neuromuscular scoliosis, relative anterior spinal overgrowth

## Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional (3D) deformity of the spine and trunk. Recent research has shed light on the role of the unique biomechanics that act on the fully upright human spine and its effect on rotational stability.[1] It has been known for a long time that, in idiopathic scoliosis, the anterior part of the spine is



longer than posterior, transforming the global thoracic kyphosis into a rotated apical lordosis.[2–4] In earlier studies, this phenomenon was called relative anterior spinal overgrowth (RASO) and was suggested to be part of the etiology of AIS.[5–7] However, recent studies have shown that this additional anterior length is present in both the primary and compensatory curves in idiopathic scoliosis, predominantly around the apex, whereas the junctional zones do not exhibit this length discrepancy, thus excluding a generalized growth disturbance.[8] Furthermore, this phenomenon was found to be located exclusively in the intervertebral disc, while the bony structures (vertebral bodies) showed an anterior-posterior ratio similar to non-scoliotic controls.[9] That finding contradicts the often cited vicious cycle theory: uneven loading of a vertebra would result in decreased growth of the loaded side in accordance with the Heuter-Volkman law causing wedging of the vertebra and subsequently even more asymmetric loading and curve increase.[10,11]. Finally, in neuromuscular (NM) scoliosis, the same phenomenon of additional anterior spinal length caused by anterior expansion of the disc was observed.[12]

These findings suggest that anterior lengthening is an integral part of a more generalized mechanism that occurs in more types of scoliosis. To confirm this hypothesis, a similar phenomenon would be expected in scoliosis of other origins. The objective of this study is to further elucidate the role of this anterior lengthening of the spine in the overall scoliotic mechanism. Therefore, we determined the anterior-posterior length discrepancy in the compensatory thoracic curves of congenital scoliosis and compared the findings with the non-scoliotic spine and major curves of AIS and NM scoliosis.

## Methods

CT-scans were included of patients in whom a short segment congenital malformation had led to a long thoracic compensatory curve without bony abnormality (Figure 1).

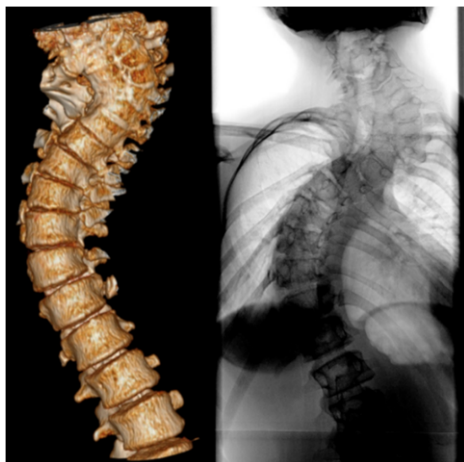


Figure 1. A reconstructed 3D image based on the CT-scan and an anterior-posterior radiograph of an included patient with congenital spinal anomalies (C2 – T6). The thoracic compensatory curve (T7 – L1, apex: disc T10/11, Cobb angle: 61°) with no congenital spinal anomalies, is the part of the spine that is analyzed in this study.

Out of 143 known congenital scoliosis patients, 18 fit the criteria, were included and compared with 30 non-scoliotic controls, 30 AIS and 30 NM scoliosis patients. Of each vertebral body and intervertebral disc in the compensatory curve, the anterior and posterior length was measured on CT-scans in the exact mid-sagittal plane, corrected for deformity in all three planes (Figure 2). The AP% was calculated for the total compensatory curve (Cobb-to-Cobb) and for the vertebral bodies and the intervertebral discs separately. Positive AP% indicated that the anterior side was longer than the posterior side.

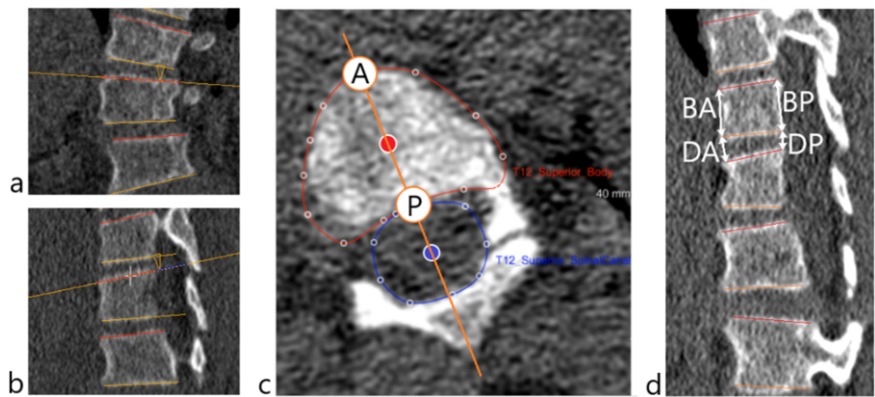


Figure 2. The method to determine the 3D orientation of the lower and upper endplates of included vertebrae in the compensatory thoracic curve is shown. CT-scans were assessed with use of semi-automatic software. First, the view was adjusted for coronal (a) and sagittal (b) tilt. Next, in the true transverse plane of the endplate, the vertebral body and spinal canal were manually segmented (c). The software automatically calculated the midpoint of the vertebral body and the spinal canal, and drew a line through both points to get the true anterior-posterior axis. The intersection of this axis with the vertebral body segmented cortex are the anterior (A) and posterior (P) landmarks of the endplate. This was done for all lower and upper endplates in the thoracic compensatory curve and 3D coordinates of all anterior and posterior landmarks were gathered. Finally, distances between them were calculated: the body-anterior (BA) length, body-posterior (BP) length, disc-anterior (DA) length and disc-posterior (DP) length (d).

**Results and Discussion**

The total AP% of the compensatory curve in congenital scoliosis showed a lordosis (+1.8%) that differed from the kyphosis in non-scoliotic controls (-3.0%;  $p<0.001$ ), and was comparable to AIS (+1.2%) and NM scoliosis (+0.5%). This anterior lengthening was not located in the bone; the vertebral body AP% showed a kyphosis (-3.2%), similar to non-scoliotic controls (-3.4%), as well as AIS (-2.5%) and NM scoliosis (-4.5%;  $p=1.000$ ). However, the disc AP% showed a lordosis (+24.3%), which sharply contrasts to the kyphotic discs of controls (-1.5%;  $p<0.001$ ), but was similar to AIS (+17.5%) and NM scoliosis (+20.5%).

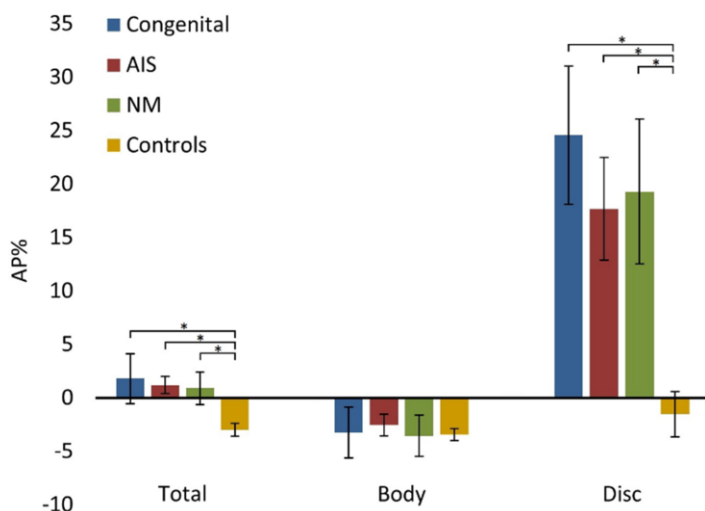


Figure 3. Results bar graph. The mean anterior-posterior length discrepancy (AP%) is shown for the total spine, the vertebral bodies and the intervertebral discs. This included the part of the spine involved in the compensatory thoracic curve in congenital scoliosis, the main thoracic curve in adolescent idiopathic scoliosis (AIS), the main thoracic curve in neuromuscular (NM) scoliosis and the corresponding levels in controls. Positive AP% indicates a larger anterior length than posterior length. The error bars indicate the 95% confidence interval of means. Significant differences are indicated with asterisks (\*).

## Conclusion and Significance

The current study on compensatory curves in congenital scoliosis expands earlier observations of anterior lengthening that appears to be part of the three-dimensional deformity in different types of scoliosis and is exclusively located in the intervertebral discs. The bony vertebral bodies maintain their kyphotic shape, which indicates that there is no active anterior bony overgrowth. Anterior lengthening appears to be a passive result of any scoliotic deformity, rather than being related to the specific cause of AIS

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# Three-dimensional reconstruction of intervertebral disc based on magnetic resonance imaging in patients with acute low back pain

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**Abstract:** The aim of the study is to evaluate the morphology of the intervertebral discs visible in the magnetic resonance image in patients with sudden severe low back pain (with or without radiation of pain to the lower limb). The second goal of the study is to perform a digital three-plane reconstruction of the intervertebral disc and to compare this technique with a standard magnetic resonance imaging test. Twenty-five patients, mean age 35.5 years, all with acute low back pain, were examined. We compared the 3D MR models with standard MRI scans by measuring seven MRI parameters. In patients with sudden, severe low back pain, with clinical symptoms suggesting an etiology within the intervertebral disc, changes in a standard MRI are found consisting of the presence of a hernia / protrusion of the intervertebral disc and lowering the height of the intervertebral disc - with lowering the disc height occurs to a greater extent in the rear section. The 3D reconstruction is a reliable 3D representation of the intervertebral disc and adjacent vertebral bodies.

**Keywords:** 3D MRI reconstruction, intervertebral discs, low back pain

## Introduction

The pathology of the intervertebral disc is one of the most common causes of acute pain in the low back pain. Magnetic resonance imaging (MRI) is the best visualization of disc disease, while three-dimensional reconstruction is not commonly performed. In order to better understand the pathology of the intervertebral disc, a semi-automatic disc visualization in a three-dimensional reconstruction was proposed, based on an algorithm developed under the NCBiR grant "Virdiamed".

The aim of the study is to evaluate the morphology of the intervertebral discs visible in the magnetic resonance image in patients with sudden severe low back pain (with or without radiation of pain to the lower limb). The second goal of the study is to perform a digital three-plane reconstruction of the intervertebral disc and to compare this technique with a standard magnetic resonance imaging test.

## Methods

Twenty-five patients, mean age 35.5 years, SD = 6.4, range 20-50 years, all with acute low back pain, were examined according to the study card (Appendix 2). They underwent an MRI (3 Tesla) of the lumbosacral spine. Three-dimensional reconstruction of the selected intervertebral disc with adjacent vertebral bodies was performed in all patients (L3 / L4 in 1 patient, L4 / L5 in 16 patients, L5 / S1 in 8 patients) (Figure 1).

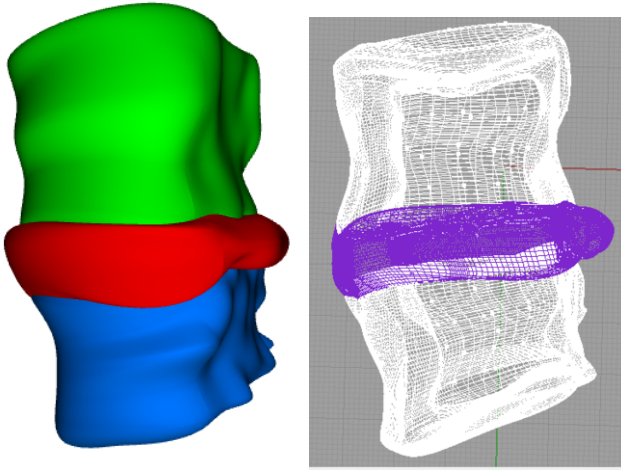


Figure 1. 3D MR reconstruction of L5/S1 spinal segment with herniated intervertebral disc.

We compared the 3D MR models with standard MRI scans by measuring the following parameters: intervertebral disc height, intervertebral disc volume, vertebral body height above the disc, vertebral body volume above the disc, vertebral body height below the disc, vertebral body volume below the disc, and intervertebral disc herniation size.

## Results and Discussion

In a clinical study, 40% of patients had palpation in the spinal processes of the lumbar vertebrae, 28% in the paraspinal muscles, and 16% in the sacroiliac joints and at the exit of the sciatic nerve from under the pear muscle. Root symptoms were present in 84% of patients.

Values obtained from 3D MR reconstruction vs. the values obtained from conventional MR images were as follows: intervertebral disc height 9.33  $\pm$  1.67 mm vs. 9.48  $\pm$  1.63 mm; intervertebral disc volume 14.11  $\pm$  4.21 cm<sup>3</sup> vs. 14.02  $\pm$  3.71 cm<sup>3</sup>; vertebra body height above the disc 27.36  $\pm$  1.93 mm vs. 27.02  $\pm$  2.05mm; volume of the vertebral body above the disc 33.86  $\pm$  7.92 cm<sup>3</sup> vs. 33.89  $\pm$  8.07 cm<sup>3</sup>; vertebral body height below the disc 26.64  $\pm$  2.19 mm vs. 26.34  $\pm$  2.03mm; volume of the vertebral body below the disc 30.38  $\pm$  6.65 cm<sup>3</sup> vs. 30.73  $\pm$  6.49 cm<sup>3</sup>; hernia size 7.84  $\pm$  2.53 mm vs. 7.57  $\pm$  2.52 mm; Only the differences in the height of individual parameters were insignificant. The herniated levels of the intervertebral disc were as follows: 68% of patients had a damaged L4 / L5 disc, 32% of L5 / S1 patients, 4% of L3 / L4 patients; 92% of the hernia was central, 4% left-sided, 4% right-sided.

The degree of damage to the intervertebral disc on the Pfirrmann scale: 56% 3<sup>rd</sup> grade, 36% 4<sup>th</sup> grade, about 4% 2<sup>nd</sup> and 5<sup>th</sup> grade. The degree of damage to the adjacent body vertebrae on the Modic scale was as follows: 68% Modic I, 28% Modic II, 4% Modic III.

## **Conclusion and Significance**

1) In patients with sudden, severe low back pain, with clinical symptoms suggesting an etiology within the intervertebral disc, changes in a standard MRI are found consisting of the presence of a hernia / protrusion of the intervertebral disc and lowering the height of the intervertebral disc - with lowering the disc height occurs to a greater extent in the rear section. 2) Three-dimensional reconstruction of the intervertebral disc is possible on the basis of a standard magnetic resonance image. 3) Comparison of conventional MRI images with 3D reconstruction images shows that the 3D reconstruction is a reliable 3D representation of the intervertebral disc and adjacent vertebral bodies.

# Age- and gender-related normative value of whole-body sagittal alignment based on 584 asymptomatic Chinese adult population from age 20 to 89

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**Abstract:** To establish the age- and sex-related normative values of sagittal alignment in asymptomatic Chinese adults, and to investigate the changes and possible associated compensation mechanisms across age groups. 584 asymptomatic Chinese adults aged 20-89 years were recruited. Subjects were grouped according to age and gender. Whole-body standing radiographs were acquired for evaluating sagittal alignment from spine to lower limb. Sagittal parameters between gender in different age groups were compared via independent t test. Pearson correlation analysis was used to demonstrate relationships between parameters. Thoracic kyphosis (TK) increased steadily while lumbar lordosis decreased gradually in both genders. Pelvic tilt (PT) in male is greater than in female across all age groups with age related gradual increase. There were significant differences between male and female from 20s to 60s in terms of knee flexion angle (KA) and ankle dorsiflexion angle (AA), but the differences were not significant after 60s. T1 pelvic angle (TPA) was significantly correlated with spinal, pelvic and lower-limb alignment. The older group ( $\geq 50$  years) had a stronger correlation of TPA with PT and KA, whereas the younger ( $< 50$  years) had stronger correlation with TK. This study comprehensively presented the normative sagittal alignment based on a large asymptomatic population, which could serve as an age- and gender-specific reference value for spine surgeons when planning for correction surgery. Age can influence the recruitment of compensation mechanism that involve more pelvic and lower limb mechanisms for elderly people.

**Keywords:** Sagittal alignment, age, gender, Chinese population

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## Introduction

The prevalence of adult spinal deformity (ASD) has been reported to be as high as 60% in the elderly population.[1] Surgical treatment of ASD patients has been increasingly performed for patients with deformity progression, neural compromise, as well as pain and functional disabilities which are not responsive to conservative treatment. One of the key goals for surgical realignment of ASD is the optimization of personalized preoperative sagittal realignment planning taking reference to the normal age and gender matched values for the specific ethnic group.[2] Previous studies have shown that populations with different ethnicity background could present with significant differences in the sagittal spinopelvic alignment. spinopelvic alignment. The normative values of whole-body sagittal alignment in Chinese adult population, however, has not been reported.

To address the knowledge gap, the objective of this study was to establish age- and gender- related normative values of whole-body sagittal alignment in asymptomatic Chinese adult population aged from 20s to 80s, and to investigate the changes and possible associated compensation mechanisms across the different age groups.

## Methods

Asymptomatic Chinese volunteers were recruited community-wide from the whole of Hong Kong through designed advertisements, flyers and recruitment brochures. Subjects were all interviewed by trained medical staff following strict protocols with criteria for inclusion of age between 20-89 years old with a validated Oswestry Disability index (ODI) scoring lower than 20%. The exclusion criteria were: 1) presence of low back pain or regular low back pain, 2) previous spine, pelvis or lower-limb pathology that could affect the spine; 3) previous surgery on spine, pelvis or lower limb; and 4) pregnancy. All subjects were subdivided into 14 groups according to age and gender. The study was approved by our institutional review board (CREC Ref. No.: 2017.689) and all participants provided written informed consent.

All subjects underwent whole body biplanar stereographs (EOS imaging, Paris, France) with a standardized radiographic protocol were acquired of each individual.[3,4] Subjects were instructed to stand in a comfortable position with hips and knees extended and with hands on a support. Sagittal radiographic parameters were measured using validated software (Surgimap, Nemaris Inc., New York, NY) for global spine and lower-limb alignment parameters (Figure 1).[5]

Data are expressed as mean  $\pm$  SD. The measurements were tabulated and analyzed using the SPSS version 19.0 software (SPSS Inc., Chicago, IL). Comparisons of means between variables were performed using unpaired Student's t test. Comparisons among age groups were made with analysis of variance, and the multiple comparisons were done. Correlations between variables were analyzed using the Pearson correlation coefficient. The level of significance was set at  $P < 0.05$ .

Results and Discussion

A total of 584 subjects were recruited and analyzed. The average age of the subjects was 50.1 years (range, 22–93) and the BMI was 24.1±6.8. The average ODI score was 6.7±4.5 (range, 0–18), indicating the asymptomatic nature of this population. Based on the findings, a comprehensive normative reference data for whole-body sagittal alignment was constructed for each gender and age group from 20s to 80s in asymptomatic Chinese adult population (see Table 1).

Table 1. Distribution of each parameter for the investigated age groups

Parameter		20-29s (n=86)	30-39s (n=81)	40-49s (n=82)	50-59s (n=86)	60-69s (n=84)	70-79s (n=81)	80s-89s (n=84)
Thoracic kyphosis	Male	24.7±9.5	22.6±7.7	25.2±7.5	26.8±8.5	28.5±7.2	28.6±8.8	30.8±13.2
	Female	23.8±8.5	23.9±8.5	27.2±8.5	27.4±8.5	27.5±8.5	28.6±8.5	29.0±8.5
	P value	0.621	0.487	0.301	0.705	0.641	0.231	0.522
Lumbar lordosis	Male	44.0±8.7	43.4±7.7	43.7±8.0	41.4±10.0	41.6±7.7	42.1±12.7	35.9±15.2
	Female	44.7±9.0	45.8±10.7	42.8±10.8	42.5±11.8	43.6±11.2	40.1±11.2	40.4±12.9
	P value	0.692	0.295	0.671	0.586	0.377	0.478	<b>0.036</b>
Pelvic tilt	Male	8.5±6.0	7.4±7.4	8.8±6.5	11.4±9.5	11.8±9.2	12.6±8.8	17.8±9.6
	Female	11.5±7.8	12.0±7.6	12.1±8.1	14.3±8.6	14.5±9.5	17.4±8.8	21.4±9.6
	P value	<b>0.040</b>	<b>0.008</b>	<b>0.050</b>	0.090	0.190	<b>0.024</b>	0.083
Pelvic incidence	Male	41.9±9.9	40.3±7.3	41.2±8.8	42.4±10.9	41.3±9.4	44.6±12.6	43.4±12.5
	Female	44.3±10.8	46.0±11.7	43.4±10.4	45.5±11.7	47.1±11.1	46.1±11.8	46.1±14.4
	P value	0.248	<b>0.022</b>	0.305	0.160	<b>0.012</b>	0.625	<b>0.001</b>
Sagittal vertical axis	Male	11.6±21.5	9.4±22.5	19.8±26.0	26.2±24.1	22.4±21.9	29.1±31.7	36.7±34.1
	Female	4.4±17.3	3.0±19.5	12.1±20.0	15.8±21.6	21.7±24.4	35.6±31.9	48.6±25.5
	P value	0.069	0.207	0.135	<b>0.019</b>	0.901	0.398	0.071
T1 pelvic angle	Male	6.8±6.0	6.2±6.2	8.1±6.7	9.6±7.1	10.7±7.8	12.4±7.7	15.7±9.8
	Female	8.5±5.7	8.7±6.5	9.7±6.8	11.5±8.2	12.8±8.5	15.8±7.9	20.7±9.6
	P value	0.153	0.083	0.283	0.226	0.251	0.077	<b>0.016</b>
Knee Flexion Angle	Male	0.0±4.7	2.9±2.9	4.2±4.2	3.2±4.5	6.9±4.8	6.7±7.5	6.6±6.3
	Female	-2.8±5.4	-0.9±4.8	0.0±4.4	-0.5±5.2	3.8±5.7	6.5±5.6	8.0±6.3
	P value	0.006	<b>0.001</b>	<b>0.000</b>	<b>0.000</b>	<b>0.009</b>	0.900	0.305
Ankle Dorsiflexion Angle	Male	1.2±2.4	3.0±2.4	3.5±3.0	3.4±3.1	5.5±3.3	4.8±3.9	4.7±3.7
	Female	1.1±3.0	1.8±2.9	2.2±2.8	2.0±3.3	4.0±3.3	5.3±3.0	5.8±3.8
	P value	0.916	0.067	<b>0.040</b>	<b>0.023</b>	<b>0.037</b>	0.565	0.171

Remarkable variability in sagittal spinal alignment with increasing age were reported in previous studies dedicated to optimizing and refining alignment target goals before surgical planning.[6,7] In the present study, advancing age led to an increase in thoracic kyphosis (TK), pelvic tilt (PT), sagittal vertical axis (SVA), T1 pelvic angle (TPA), knee flexion angle (KA), ankle dorsiflexion angle (AA) and a decrease in lumbar lordosis (LL). A sudden increase was seen from 60s in KA and AA, as a compensatory mechanics to maintain global for sagittal balance, since a large increase of TPA and SVA was also presented since 60s, indicating that the compensation mechanisms for the concurrent LL decrease were not sufficient (see Table 1 and Figure 1).

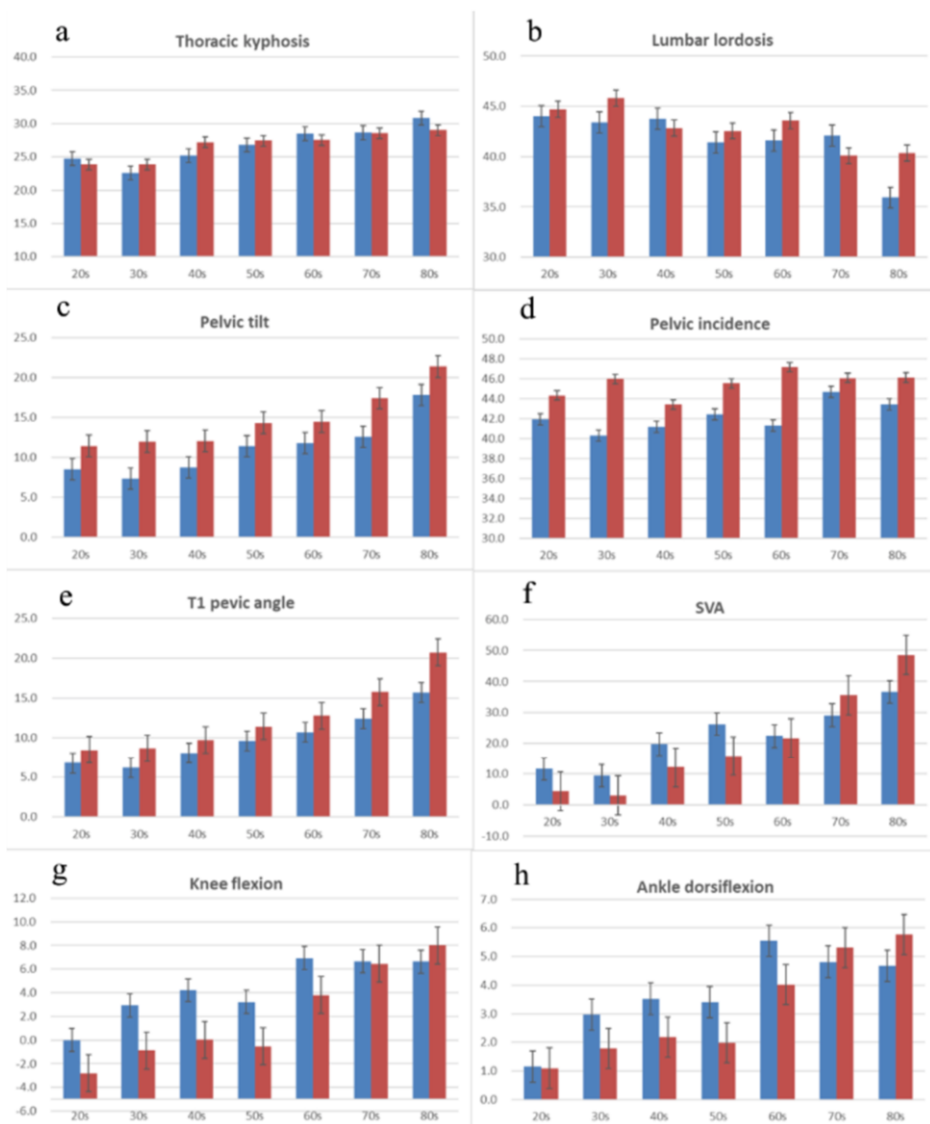


Figure 1. Changes in spinal, pelvic, global and lower-limb alignment parameters with age in male and female.

By correlating radiographic measurements to age, we are able to provide support for these compensatory changes even in an asymptomatic group of volunteers. In our study, increasing age was correlated to decreasing LL and increasing PI, LL, PT, TK, PT and KA. (see Table 1) These age-related changes also reflect our current understanding of sagittal balance—a decrease in LL and resultant increase in PI-LL mismatch triggers increases in PT and KA as a means of compensation.

Gender-related alignment difference have been contradictory in previous studies. Vialle *et al.*[8] showed that female subjects had higher values in lumbar lordosis and PI. On the other hand, MacThiong *et al.* reported that there was no difference in PI, SS and PT between males and females. The current study found that there was a large gender

difference in pelvic morphology (PT and PI), which is in accordance with Yukawa’s study (see Table 1).[9]

With the popularity of EOS whole-body radiographs, methods of postural compensation have been gaining more attention recently.[10,11] Recruitment of lower extremity compensation to counteract sagittal spinal deformity and loss of upright posture is an increasingly well-recognized phenomenon.[12] In our study, a chain of sagittal alignment correlation reflecting compensation mechanism from spine to lower limb was established (see Table 2). Global alignment parameters including TPA and SVA were significantly correlated with spinal, pelvic and lower-limb alignment, of which TPA had a stronger correlation with each of these parameters as compared with SVA. In comparison, the older group had a stronger correlation of TPA with PT and KA, whereas the younger group had stronger correlation with TK (see Table 3). All sagittal parameters were correlated with age.

Table 2. Correlation coefficient between radiographic variables

	TK	LL	PT	PI	SVA	TPA	KA	AA	Age
TK	-	0.334**	-0.045	-0.014	0.025	-0.041	0.089*	0.113**	0.175**
LL	0.334**	-	-0.193**	0.463**	-0.142**	-0.180**	-0.028	-0.023	-0.172**
PT	-0.045	-0.193**	-	0.638**	0.311**	0.877**	0.100*	0.138**	0.333**
PI	-0.014	0.463**	0.638**	-	0.304**	0.639**	0.071	0.053	0.124**
SVA	0.025	-0.142**	0.311**	0.304**	-	0.601**	0.358**	0.129**	0.425**
TPA	-0.041	-0.180**	0.877**	0.639**	0.601**	-	0.197**	0.137**	0.409**
KA	0.089*	-0.028	0.100*	0.071	0.358**	0.197**	-	0.792**	0.475**
AA	0.113**	-0.023	0.138**	0.053	0.129**	0.137**	0.792**	-	0.405**
Age	0.175**	-0.172**	0.333**	0.124**	0.425**	0.409**	0.475**	0.405**	-

TK: Thoracic kyphosis (T5–T12), LL: lumbar lordosis, SS: sacral slope, PT: pelvic tilt, PI: pelvic incidence, SVA: sagittal vertical axis, TPA: T1 pelvic angle, KA: knee flexion angle, AA: Ankle dorsiflexion angle  
\*: Correlation is significant at the 0.05 level.; \*\*: Correlation is significant at the 0.01 level.

Table 3. Correlation coefficient between TPA and other radiographic variables in younger and older groups.

	TPA	
	Younger	Older
TK	-.125*	-.091
LL	-.121	-.156**
PT	.843**	.876**
PI	.614**	.659**
KA	-.138*	.190**
AA	-.147*	.112*

\*\* : Correlation is significant at the 0.01 level.  
\* : Correlation is significant at the 0.05 level.

Conclusion and Significance

This study presented a comprehensive study of whole-body sagittal alignment based on a large cohort of asymptomatic population, which could serve as an age- and gender-specific reference value for spine surgeons when assessing and planning for potential correction surgery. Age can influence the recruitment of compensation mechanism that involve more pelvic and lower limb mechanisms for elderly people.

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# Chapter 4

## Imaging and 3D Measurements: Surface Topography

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# Eliminating 2D spinal assessments and embracing 3D and 4D: clinical application of surface topography

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**Abstract:** The Adams Forward Bend Test recognizes the rotational aspect of the curve with the spine in flexion, and the AP X-ray measures the coronal plane deviation by using the Cobb Angle. However, modern techniques including CT-scan, biplanar radiograph, ultrasound, and surface topography allow the clinician to better evaluate and visualize the true 3-D nature of the spine. Surface Topography imaging uses the surface of the trunk to estimate the spine position using a mathematical algorithm that has been found to be accurate when compared to the radiologic Cobb Angle. The sagittal balance of the spine measured by surface topography is compared in three different situations, namely, “standing up straight,” “standing relaxed,” and “walking,” which will help to best assess posture and risk of proximal junctional kyphosis before and after the treatment. Coronal imbalance (lateral deviation) and a range of maximal vertebral surface rotation (amplitude in either direction) are considered as the parameters with an excellent to good reproducibility. COP displacement or symmetry from the midline is used to measure the stability of the trunk. Therefore, those selected spine shape parameters and COP deviation would be considered as the best descriptors in the assessment of postural sway and outcome of PSSE in children with AIS.

**Keywords:** Surface topography, center of pressure, spine shape parameters, posture, AIS

## Various 3-D modalities for spinal measurements

The assessment of scoliosis has progressed over the decades as we realized the importance of the three-dimensional characteristics of the spinal curve. The Adams Forward Bend Test recognized the rotational aspect of the curve with the spine in flexion, and the AP X-ray measured the coronal plane deviation by using the Cobb Angle. But modern techniques allow the clinician to better evaluate and visualize the true 3-D nature of the spine.

The Cobb Angle, which was once the gold standard in the measurement of scoliosis, is significantly influenced by patient positioning during the x-ray procedure. Any rotation in the patient's trunk during positioning changes the image's relationship to the plane of maximal deformity and can change the measurement of the Cobb Angle significantly.

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The CT Scan allows the clinician to rotate the 3-D image into the plane of maximal deformity to measure the Cobb Angle, thus giving a more accurate measurement of the true magnitude. But the CT scan is taken supine, which changes the effect of gravity on the spinal curve, and it also carries the highest level of radiation exposure of the imaging modalities.

New slit scan technology allows a simultaneous AP and Lateral x-ray to be taken at very low radiation dose, and a 3-D reconstruction to be performed using those two images. This reduces x-ray exposure and delivers a standing 3-D image that includes the influence of gravity.

Ultrasound is now also used to image the spine, delivering zero radiation dosage, but without the true 3-D imaging capacity of the other modalities.

Surface Topography imaging uses the surface of the trunk to estimate the spine position using a mathematical algorithm that has been found to be accurate with the radiologic Cobb Angle. But it is not able to see the structural changes that might be present in the vertebrae.

### **Surface topography to quantify aesthetic and dynamic trunk asymmetry and posture**

As the treatment of scoliosis has become more patient-focused, the assessment of the trunk shape and symmetry have become more important. While the Cobb Angle may be important to the clinician, the aesthetic appearance of the trunk is what the patient sees when they look at their body. Quantification of the symmetry or asymmetry is being done using photographs and surface topography measurements to help in this assessment.

Measurement of the spine in motion is the next challenge for the clinician. Static measurements of the patient standing for imaging may not illustrate the normal habitual posture that the patient maintains when engaged in activities of daily living. Radiographic techniques like fluoroscopy are not practical for this purpose and would deliver too much x-ray exposure. Ultrasound is not possible during movement. But surface topography is being used to watch spinal motion in real time while the patient walks on a treadmill.

### **Dynamic evaluation to better assess pre-treatment posture**

In this example, the sagittal balance of the spine is compared in three circumstances: first with the patient “standing straight” as they are often told to do during x-ray examination; second, with the patient in their relaxed, habitual standing posture; and third, while walking at a comfortable pace on a treadmill. The kyphosis and sagittal balance are substantially different in the three measurements, leading the clinician to consider whether standing radiographs are really the best assessment of posture and risk of proximal junctional kyphosis in the surgical evaluation.



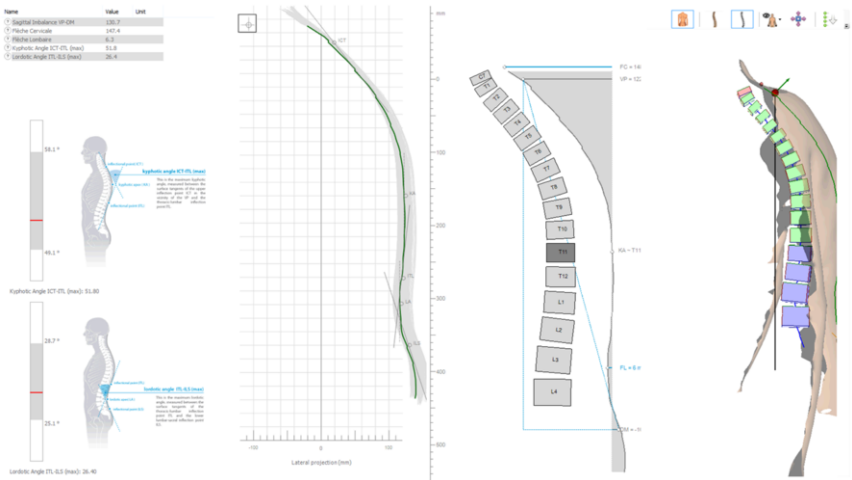


Figure 3. Same patient while walking, showing markedly larger thoracic kyphosis (green line) and very forward sagittal balance.

Improve the outcome of Physiotherapy Scoliosis-Specific Exercises (PSSE)

Studying the spine in motion can also help with teaching and assessment of physical therapy exercises for patients. The visual feedback it offers can help the patient see how their posture changes with activation of certain muscle groups or with strengthening over time.

In this next example, a 12-year-old boy was diagnosed with Adolescent Idiopathic Scoliosis (AIS) and complained of thoracic back pain. His pain increased with prolonged sitting, standing, and activities. His major Cobb angle (T5-T12) was 18°. Postural Asymmetries at thoracic side bending and rotation were examined. Reduced forced vital capacity with limited rib cage expansion or mobility was noticed. Decreased strength at the hips, core, scapular region was found. Decreased active ROM at the thoracic spine, lumbar spine, shoulder or scapular region were recorded. Oswestry Modified Pain Patient Questionnaire was 44% disability. Spine stabilization, Schroth and scoliosis specific exercises were recommended. He was evaluated before and after 12 weeks PSSE using a surface topography system.

He was gradually responding with improved awareness of postural correction with or without visual input. His pain was significantly reduced from 7/10 to 3/10. He reported less spasms. Surface topography motion analysis demonstrated steady improvements, including reduced coronal imbalance, maximal apical deviation, pelvic obliquity, maximal vertebral rotation, and pelvic rotation from -25% to -100% (see Table 1 and Figure 4). In the sagittal plane, there were mild increased imbalance and pelvic inclination. COP butterfly showed reduced alterations in both AP and M-L direction. However, there were no changes in COP oscillation after PSSE.

Table 1: Changes in 3D alignments and center of pressures following 12 weeks PSSE (% , mean or standard deviation-SD)

Parameters	Pre-PSSE Mean	Post-PSSE Mean	% Change
Coronal plane			
Coronal Imbalance (mm)	6	1	-83
Max Apical Deviation (mm)	20	15	-25
Pelvic Obliquity (°)	2	0	-100
Sagittal plane			
Sagittal Imbalance (mm)	95	120	26
Pelvic Inclination (°)	21	23	9.5
Transverse plane			
Max Vertebral Rotation (°)	8	1	-87.5
Pelvic Rotation (°)	2	0	-100
Parameters	Pre-PSSE SD	Post-PSSE SD	% Change
COP			
A/P Position (mm)	0.81	0.50	-38.3
M/L Position (mm)	1.91	0.90	-52.9
L Oscillation (cm)	12.7	12.7	0
R Oscillation (cm)	12.7	12.7	0

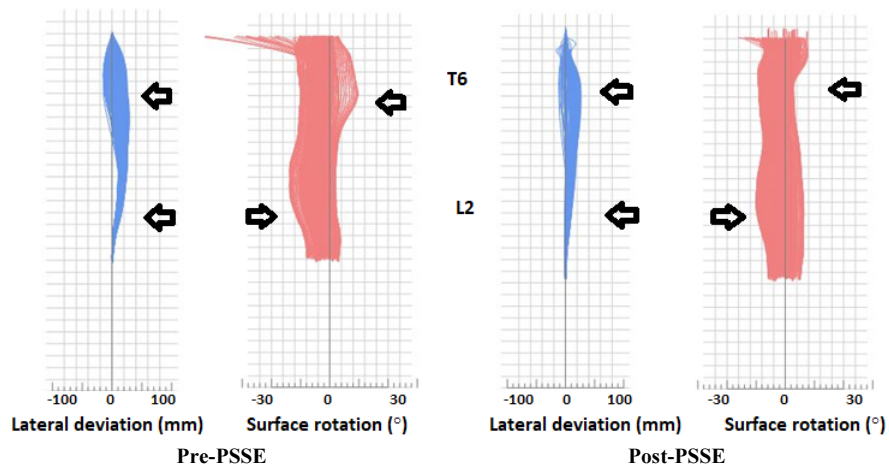


Figure 4. Comparison of a range of lateral deviation from the midline and vertebral surface rotation during walking at 2 miles per hour: significantly reduced range of lateral deviation (blue color) at T6 and L2 (arrows) or maximal vertebral surface rotation (red color) at T6 (arrows) before PSSE (left) vs. after PSSE (right).

Given the evidence with maximally reduced lateral deviations and vertebral surface rotations in spine as well as decreased ranges of these parameters during walking, it indicates that PSSE may improve spinal malalignment and postural sway. Dynamic plantar pressure with reduced alterations of COP in AP and ML further implies PSSE may be helpful in the improvement of balance.

## Conclusions

Three-dimensional evaluation of posture is necessary to thoroughly understand spinal deformity, and 3D evaluation during walking (4D) may offer even deeper understanding of spinal function. Coronal imbalance (lateral deviation) and a range of maximal vertebral surface rotation (amplitude) have been found recently to have excellent to good reproducibility between days.[1] However, older studies suggested these parameters should be used with caution while monitoring posture over time.[2] Thoracic kyphosis with an excellent reliability and a high to moderate validity could be utilized for clinical follow-up in the evaluation of sagittal balance.[3] COP displacement or symmetry from the midline can be used to measure stability,[4] and our COP butterfly pattern reflects the symmetry and deviation of COP while ambulating from a single-limb stance to a double-limb stance transition. Therefore, those selected spine shape parameters and COP deviation would be considered the best descriptors in the assessment of postural sway and outcome of PSSE in children with AIS.

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# Effect of adjunct thoracoplasty on Adolescent Idiopathic Scoliosis patients' 3D back contour

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**Abstract:** The aims of this study were to evaluate the effect of a thoracoplasty procedure in addition to a posterior spinal fusion and instrumentation on an Adolescent Idiopathic Scoliosis (AIS) patient's 3D back contour as measured by surface topography. We performed a retrospective review to identify patients who were treated with posterior spinal fusion with spinal instrumentation and those who were treated with an additional thoracoplasty procedure. We analyzed changes in surface topography measurements between these two groups using t-test and ANCOVA statistical analyses. Although there were no statistically significant differences in 11 of 12 variables, thoracoplasty-posterior spinal fusion (n=10) group had a mean 6.6 unit reduction in trunk asymmetry while the posterior spinal fusion group (n=26) had a mean 22.8 unit reduction in trunk asymmetry (p-value<0.05). The posterior spinal fusion group and thoracoplasty-posterior spinal fusion group were not shown to have clinically significant differences in 3D back contour correction. An additional thoracoplasty procedure does not provide better correction in the transverse plane and in fact had a smaller degree of trunk asymmetry correction. This supports the current trends of decreasing use of thoracoplasty in AIS patients to address severe rib hump deformities given concerns for decreased post-operative lung function and alternative methods of vertebral body derotation, such as thoracic pedicle screws.

**Keywords:** Adolescent idiopathic scoliosis; thoracoplasty; surface topography; 3D back contour

## Introduction

Adolescent idiopathic scoliosis (AIS) affects 2-3% of children in the United States and can lead to visible deformity, emotional distress, and respiratory impairment from rib deformity.[1] The Scoliosis Research Society recommends that clinicians strongly consider surgery when an AIS patient's Cobb angle is greater than 40 degrees.[2-4] In addition to a posterior spinal fusion (PSF) and instrumentation, surgeons may also perform a thoracoplasty (TP), an elective procedure to resect the ribs from the costovertebral joint to the posterior axillary line or a short apical rib for addressing a rib prominence.[5, 6] However, over the past 20 years, use of the TP procedure has steadily declined, ranging from 76% of AIS cases in the 1990s to 20.3% in 2013.[6] Surgeons have reduced their utilization of TP due to concerns of compromising pulmonary

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function and the possibility of achieving superior vertebral derotation with thoracic pedicle screws.

Surface topography (ST) scanning allows clinicians to assess 3D asymmetries of back contour and provide some measurable parameters which cannot be obtained from traditional PA full column radiographs.[2,7,8] The aims of this study are: 1) to compare the 3D ST measurements between AIS patients who were treated with TP in addition to a PSF procedure (TP-PSF) with those who were only treated with a PSF procedure (PSF); 2) to determine the changes of the 3D ST measurements before and after the surgical intervention in the TP-PSF and PSF group, respectively.

Methods

This study involved a retrospective review of a hospital’s database, screening for patients with the following criteria: diagnosis of AIS, age 10-19, treatment with PSF and spinal instrumentation with or without TP, and has both preoperative and postoperative radiographic and surface topographic data with a minimum 6 month follow up after surgery. Data from the charts were extracted, including demographics, preoperative and postoperative MTS measurements, preoperative and postoperative radiographic measurements, and operative information. We had a total of 36 patients, TP-PSF group (n=10) and the PSF group (n=26). Pre-operative measurements between the two group were comparable (Table 1). 3D Back Contour measurements using ST: The operators measured the degree of asymmetry of the patient’s 3D back contour using the Milwaukee Topographic System (MTS) (Children’s Hospital, Milwaukee, WI). The operator would scan the patient’s back, left flank, and right flank vertically with the scanner approximately 20cm from the surface.[11] A total of twelve parameters were measured with the MTS: T1-S1 angle, T1-S1 deviation, T1-NC angle, T1-NC deviation, AP-Q angle, pelvic tilt angle, axial surface rotation angle, left or right percentage of area of back, Suzuki hump sum (rib hump index), kyphosis, lordosis, and trunk asymmetry.[12]

Table 1: Demographics for PSF and TP-PSF group (Mean)

Variable	PSF group (n=26)	TP-PSF Group (n=10)
Age at surgery (years)	14.3	14
Male	3	0
Female	23	10
Pre-op thoracic Cobb angle	49.9°	48.9°
Post-op thoracic Cobb angle	18.6	21.4°
Pre-op thoracolumbar Cobb angle	53.5°	47.4°
Post-op thoracolumbar Cobb angle	17.3°	17.5°
Follow up time (years)	1.81	2.90

PSF=Posterior Spinal Fusion; TP-PSF=Thoracoplasty-Posterior Spinal Fusion



We used the descriptive method to calculate the mean and standard deviation (SD) for each parameter. Then, we analyzed the data using student t-test and ANCOVA statistical analyses. We considered measurements with a p-value <0.05 to be statistically significant.

## Results and Discussion

Except that the TP-PSF group had a mean 6.6 unit reduction in trunk asymmetry as compared to a mean 22.8 unit reduction in the PSF group (p-value<0.05), we did not find statistically significant differences in the other eleven variables between these two groups (see Table 2). However, we did notice reductions in axial surface rotation in the thoracic region in both groups and reduction in the lumbar region in PSF group. (p-value>0.05).

Table 2: Comparison of differences between pre and post ST measurements in PSF group with those in TP-PSF group (Mean  $\pm$  SD, Student t-test, ANCOVA)

Parameters	Differences in PSF Group	Differences in TP-PSF Group	P-value
T1-S1 Angle	-0.8° $\pm$ 1.8°	0.0° $\pm$ 3.2°	0.08
T1-S1 Deviation	-4.0 $\pm$ 11.6	-2.8 $\pm$ 16.3	0.56
T1-NC Angle	-1.2° $\pm$ 1.8°	-0.6° $\pm$ 2.2°	0.24
Thoracic Q angle	-24.6° $\pm$ 12.3°	-22.7° $\pm$ 7.2°	0.62
Thoracolumbar Q angle	-22.8° $\pm$ 9.9°	-27.4° $\pm$ 16.7°	0.70
Pelvic Tilt	-3.7 $\pm$ 10.4	0.4 $\pm$ 2.1	0.88
Left area (% of back)	0.9 $\pm$ 6.0	2.5 $\pm$ 5.3	0.90
Right area (% of back)	-0.9 $\pm$ 6.0	-2.5 $\pm$ 5.3	0.91
Suzuki Hump Sum	-5.6 $\pm$ 7.7	-4.4 $\pm$ 14.9	0.26
Kyphosis Q angle	-1.2° $\pm$ 13.1°	-5.7° $\pm$ 9.7°	0.54
Lordosis Q angle	1.3° $\pm$ 8.4°	0.4° $\pm$ 9.7°	0.81
Trunk Asymmetry	-22.8 $\pm$ 20.5	-6.6 $\pm$ 19.3	0.02*

\* indicates statistically significant value with p value <0.05

<sup>a</sup> The values for T1-NC deviation and rotation angle were not analyzed because there were not enough data points to run the analysis (n<5).

PSF=Posterior Spinal Fusion

TP-PSF=Thoracoplasty-Posterior Spinal Fusion

Both the PSF group and TP-PSF group demonstrated statistically significant reduction in thoracic and thoracolumbar Q angles before and after the spinal surgery as measured by ST (P<0.05). The thoracic Q angle was changed from 35.1° to 10.5° in the PSF group and from 34.2° to 11.5° in the TP-PSF group, and the thoracolumbar Q angle was altered from 34.5° to 11.8° in the PSF group and from 38.8° to 11.3° in the TP-PSF group. In addition to a profound reduction of curves, the PSF group also presented with

significant reductions in the coronal plane malalignment, rib hump sum, and shoulder level asymmetry ( $P < 0.05$ ). In the PSF group, the T1-S1 Angle is reduced from  $2.3^\circ$  to  $1.4^\circ$ . The T1-NC Angle is reduced from  $2.3^\circ$  to  $1.1^\circ$ . The Suzuki Hump Sum is reduced from 16.6 to 11.0 as well as asymmetry from 43.1 to 20.3 (see Figure 1).

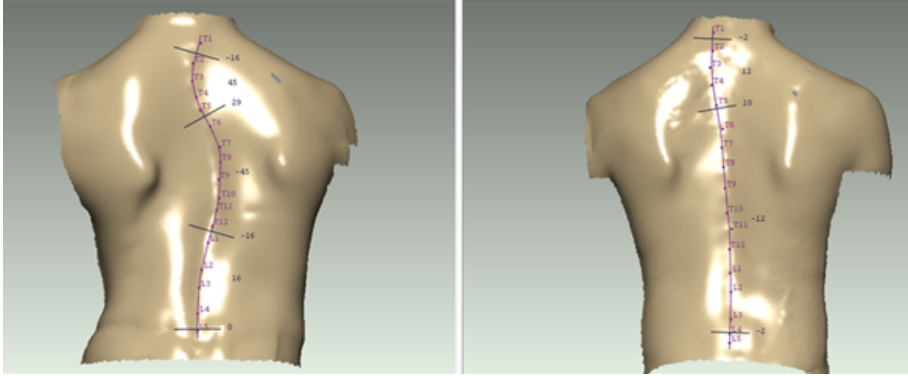


Figure 1. After posterior spinal fusion with spinal instrumentation, the patient had reduced shoulder asymmetry, rib hump, trunk asymmetry, and curve deformity as measured in the coronal plane using ST in addition to thoracic Cobb angle reduction from  $46^\circ$  to  $8^\circ$  in the coronal plane.

Overall the improvement was similar in the parameters such as curve of the back, kyphosis, lordosis, and Suzuki hump sum. Our results show that both the PSF and TP-PSF procedure are effective in the correction of 3D trunk deviations from the midline and curvatures in children with AIS. While the Suzuki hump sum did not demonstrate significant differences between the two procedures, it is an assessment of rib prominence at three levels in the thoracic region. Thus, it may not be altered significantly after a TP performed at the apical vertebra. This unexpected result could be due to our relatively small sample size in the TP-PSF group. Alternatively, the patients that received a TP could have had greater perceived asymmetry than those who were treated with the PSF alone, making it more difficult to correct with surgery.

Our results differed from those of Suk et al. who showed that an additional TP procedure (57% correction) was more effective than PSF alone (35% correction) in reducing the rib hump prominence when measured in a forward bending position.[13] However, we evaluated patients in an upright position with ST. Chunguang et al. also demonstrated that patients undergoing a TP had experienced a significant correction in asymmetry in the forward-bending position but they also demonstrated worsening pulmonary function test measurements post-operatively.[14]

While patients treated with a brace despite have similar post-operative Cobb angles, patients who are treated only surgically had higher scores on the self-image appearance, although it is minimal: 0.2 points on a 5 point scale.[15] Furthermore, surgical treatment of AIS is generally considered to be safe with a post-operative complication rate of 6% with a mortality rate of 0.05%.[16] The patient's improvement in self-image appearance and low surgical complication rate make surgery a favorable treatment option. A previous study by Thometz et al. has shown significant improvements in lateral curvature, trunk rotation, and topographic deformity in patients who underwent posterior spinal fusion using surface topography.[17] Our current study shows that both the TP-PSF and PSF procedures improve the cosmetic appearance of the trunk.

## Conclusion and Significance

As a conclusion of this study, both the TP-PSF and PSF procedure result in a significant correction of the 3D trunk deformities. Additional TP has not yielded remarkable cosmetic improvements to the patient's rib prominence. However, the improvement in rib hump index measures was similar. Given the fact that there are no significant differences of 3D back contour post-surgery between two procedures, our study supports the current trend that the additional TP is no longer a necessary procedure when the primary aim is to merely reduce the rib hump in children with AIS. For moderate curves undergoing surgical correction, the TP did not result in statistically significant benefits. In contrast, this invasive procedure could be utilized electively when considering the severity of the patient's rib prominence, degree of vertebral derotation required, and the patient's baseline pulmonary function.

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# Vertebra prominence in women: significance in clinical practice and in surface topography

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**Abstract:** A sexual dimorphism (SD) of the "vertebra prominens" was found, namely the 7<sup>th</sup> cervical vertebra (C7) spinous process (SP) is more frequently longer in men and the 1<sup>st</sup> thoracic (T1) SP in women.[1] We assume that the cause of this SD is the different anatomy of the anterior upper thoracic region (AUTR) between men and women, due to the presence of the breast. One-hundred forty-two women aged 48.1±17 years old, who visited the OPD for neck complaints, were studied. Measures included the age, the relationship of C7 and T1 SP length, documented in three types (type 1 = [C7 > T1], 2 = [C7 = T1], 3 = [C7 < T1]), the breast size, (small, medium and large), the length ratio of C7/T1 SP and the BMI. Breast size and SP length relationship between C7 and T1 was found to be significantly correlated. The results confirm that the cause of the SD of the SP length of C7 and T1 seems to be the different female AUTR anatomy due to the presence of the breast and it is probably the result of the need of the posterior cervical anatomical structures to compensate for the higher torque created by the female AUTR anatomy. These original findings are useful in clinical examination, in breast oncology, for the plastic surgeons, in terms of implantation of the proper breast size implant, after mastectomies for malignancies but also for aesthetic reasons and the software of all surface topography devices should be adjusted accordingly.

**Keywords:** vertebra prominens, sexual dimorphism, seventh cervical vertebra spinous process, first thoracic vertebra spinous process, breast.

## Introduction

The 7<sup>th</sup> cervical vertebra is traditionally named "vertebra prominens", as it is the one with the longest spinous process (SP) (Figure 1). [2,3] The ligamentum nuchae is attached to its SP. This SP is a guide point during the clinical examination and all trunk surface topography apparatuses use the C7 as the anatomical guide point in their software.

We decided to confirm the accuracy of this traditional knowledge by studying the corresponding morphology according to gender. This was due to the finding that in some lateral radiographs of the cervico-thoracic junction, the SP of T1 was longer mainly in female patients, some of whom suffered from neck or posterior thoracic pain. It was documented in this study that in men the longer and prominent SP is more often that of C7, while in women that of T1 vertebra (Figure 1).[1]

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Figure 1. Lateral radiograph of a woman showing a longer T1 SP.

These anatomical differences of the length of the SP of C7 and T1 are now described numerically,[1] for the first time in the literature, as to our knowledge there is no previous study on this issue. These novel findings lead to the necessity to shed light on the cause of this SD, in terms of the different length of the SP of C7 and T1 vertebrae. We assume that the cause of this SD is the different anatomy of the anterior upper thoracic region between men and women, due to the presence of the breast in women. The existence of the breast leads to the formation of a longer T1 SP. This study attempts to confirm this statement.

## Methods

The study protocol was approved by the hospital ethical committee (Excerpt from the 32<sup>nd</sup> Ethical committee meeting of 16<sup>th</sup> of April, 2019), and a group of women were examined after consent.

### *Participants*

One-hundred forty-two women, of a mean age of  $48.1 \pm 17$  years, who visited the OPD for neck complaints, were included in the study. Those who had neck injuries or neoplastic disease were not included.

### *The documented parameters*

The measures included a) age b) relationship of C7 and T1 SP length measured in the cervico-thoracic area of the lateral spinal radiographs, documented as *type 1* if SP of C7 > T1, *type 2* if C7 = T1 and *type 3* if C7 < T1, (c) breast size, whereby *small size* was defined as *type 1*, *medium size* as *type 2* and *large size* as *type 3*, according to the Triumph bra manufacturer's classification, d) length ratio of C7/T1 SP, and e) BMI, whereby "Underweight" corresponded to a BMI < 19, "Normal Weight" to a BMI of 19-25, and "Overweight or Obese" to a BMI > 25.

### *Statistical analysis*

Power analysis was performed in order to detect statistically significant (SS) differences higher than 10% between the categories of interest at a significance level of

p<0.05, with 80% statistical power. According to the analysis, the required sample should consist of at least 126 participants in total. All categorical variables are shown as absolute (N) and relative (%) frequencies. Continuous variables are described as mean ± standard deviation. The association between categorical variables was assessed using Pearson’s  $\chi^2$  or Fisher’s exact statistics. Multiple ordered logistic regression was used in order to evaluate the effect of the breast type and of the age on the SP C7/T1 length ratio types. All tests were two-sided and were considered significant if p<0.05. Stata® v.16.0 statistical software was used for the analysis, except for the correlation of BMI to C/T length ratio, which was calculated using the Microsoft Excel correlation function.

Results and Discussion

The descriptive characteristics of the sample are shown in table 1.

Table1. Sample characteristics

		N	%
Breast type	Small (1)	23	16.2%
	Average (2)	56	39.4%
	Large (3)	63	44.4%
C/T Relationship	C7>T1	19	13.4%
	C7=T1	38	26,7%
	C7<T1	85	59.9%
BMI	Underweight	21	14.9%
	Norm weight	58	41.1%
	Overweight/obese	62	44.0%
		Mean	Standard Deviation
Age		46.8	17.7
C/T length Ratio		.95	.06

The majority (60.9%) of women with small breasts had a type 1 C/T length ratio. On the other hand, the majority (96.8%) of women with a large breast had a type 3 C/T length ratio (Table 2, p<0.001).

Table 2. Breast size and C/T SP length relationship, p<0.001

		Breast		Average		Large	
		Small		(2)		(3)	
		(1)					
		N	%	N	%	N	%
C/T Relationship	C7>T1	14	60.9%	5	8.9%	0	0.0%
	C7=T1	4	17.4%	32	57.1%	2	3.2%
	C7<T1	5	21.7%	19	33.9%	61	96.8%

Multiple ordered logistic regression on the C7/T1 SP length ratio, adjusting for age, revealed that women with large breast were 8.7 times more likely to have C7<T1 SP (type 3) versus the combined type 1 and, type 2 categories than women with small breast, (p=0.039) (Table 3).

Table 3. Multiple ordered logistic regression on SP C7/T1 length ratio (dependent variable)

		Odds ratio	Standard error	95% Confidence Interval	p
Breast size	Small (reference)				
	Average	0.332	0.262	0.071 1.556	0.162
	Large	8.653	9.058	1.112 67.333	0.039
Age		0.976	0.015	0.947 1.005	0.109

The correlation of BMI to C/T length ratio was weak, (r= -0,430331) showing that weight and height do not practically influence the C/T SP length ratio.

The study of the anatomy of the cervico-thoracic junction in quadrupeds such as horses or elephants showed that the prominent vertebra is T3 or T4 or even T5 depending on the species (Figure 2).

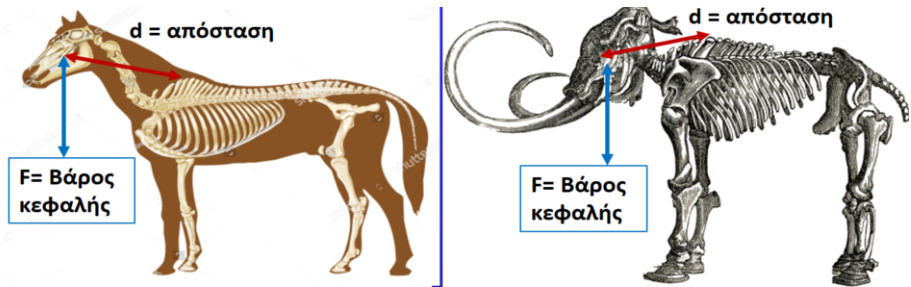


Figure 2. The torque [moment] created by the weight of the head is the product of the force F [weighty of head] by the distance d [moment arm], (torque = F x d in Nm). The distance d and the weight in humans are much smaller. The horse's head weighs about 10% of the horse's body weight. An animal weighing 280 kg will have a head weight of 28-30 kg. The elephant's head weighs a lot more. In horses, the prominent SP is that of T4, as shown in the picture, while in elephants that of T5. d refers to the distance from the center of weight of the head to the apex of SP where the ligamentum nuchae is attached.

We assume that this anatomy in mammal quadrupeds is linked to the need to balance the large torque created due to the heavier head, by the posterior anatomical structures (ligaments, muscles and bones) in the cervical and upper thoracic spine.

In humans, due to the upright posture and bipedal gait, there is no great need to balance such a large torque, because the head is lighter (about 4 kg on average) and the lever arm is shorter (shorter neck length of humans). We assume (hypothesize) that in the course of evolution, in humans with a lighter head and shorter neck compared to quadrupeds, a prominent SP should be formed in a vertebra closer to the head, and actually this is either C7 or T1, as we found. In women, however, in line with the above, there is still the need to balance by their posterior cervical structures a greater torque, which is created by the anterior thoracic anatomical structures, but of course on a smaller scale compared to the quadrupeds. We assume that this is due to the existence of the breasts, which increase the weight of the anterior upper thorax and must be compensated for by their posterior anatomical structures in the neck, Figure 3.

In women with overdeveloped breast, the weight (F) of the anatomical configuration of the anterior upper thoracic region increases and thus the anterior torque becomes much greater. In this case, as well as in the case of an average breast size, this increased torque would be compensated more effectively from the posterior cervical structures if the spinous process, where the ligamentum nuchae is attached, is that of a vertebra more

caudal from the base of the skull and such is reasonable to be that of T1. Based on this theoretical interpretation, the findings of our earlier research,[1] could be explained.

Women with hypertrophic breasts have been reported to complain of posterior thoracic pain, back pain and other discomforts.[4] In these women the posture is also modified.[5,6] After reducing the size of the breast with mastoplasty, cervical lordosis, thoracic kyphosis, and lumbar lordosis improve and patients' neck pain and back pain decrease. Moreover, symptoms of depression due to the large breast size also decreased. Quality of life parameters, including physical activity, socialization, fatigue, sleep, and emotional responses, also showed significant improvement.[7]

The reported postural changes after breast reduction are due to changes in body mass as well as to the effects of physical and psychological factors on posture. Indeed, breast hypertrophy is often associated with kyphosis, as patients try to hide what they consider to be a source of embarrassment. A new breast eliminates previous dissatisfaction with body image, reduces anxiety, and increases self-esteem. Improvements in body image and reduced weight in the anterior part of the body help to correct this postural disorder.[8] Yet it was reported that there were significant reductions in pain at pre and post in the neck, cervical spine, back, shoulder and arm ( $p < 0.05$ ), following mammoplasty, and improvement in body posture, primarily in the alignment of shoulders, trunk and pelvis, and a decrease in pain in the upper limbs and spine, were observed.[9]

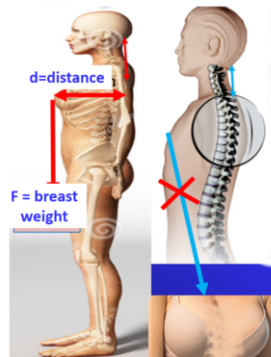


Figure 3. In women, there is a need to balance the different torque created between the anterior thoracic anatomical structures (anteriorly higher  $F$  and  $d$  in females than males), and the posterior cervical structures. The different torque between women and men is created due to the presence of the breasts, which increase the weight ( $F$ ) and lengthen the lever arm ( $d$ ) of the torque at the anterior upper thorax in women, which must be compensated by the posterior anatomical structures in their neck.

## Conclusion and Significance

The results of this study may prove very useful in similar cases, in order to validate to what degree the anatomy of their cervical-thoracic junction could be responsible for the above-mentioned discomforts.

A major contribution of the findings of this study to clinical practice is the following. It is known that mastectomies in cases of breast malignancies are now in the daily routine of gynecologists and general surgeons. Many of these women resort to breast augmentation for psychological and aesthetic reasons. Also, many women today, for sexual and psychological reasons, resort to plastic surgeons to increase the size of their breasts with breast prostheses. In all these cases, the surgeons must check which is the



prominent vertebra and then choose the corresponding reasonable size of the breast prosthesis. Otherwise, if they resort to the larger size, for example, for a woman with a C7 vertebra prominent, she will most likely have long term problems due to the inconsistency of the prosthesis size with the type of her cervico-thoracic anatomy. The documentation of the anatomy of this area is also necessary for the improvement of the operation of the surface topography devices. Today, these devices use the C7 as the prominent vertebra in their software, which should not be applied to all the examined persons but accordingly adjusted.

Finally, it should be noted that to our knowledge, no similar study has been reported to date.

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## Chapter 5

# Imaging and 3D Measurements: Ultrasound

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# Accuracy of pedicle localization using a 3D ultrasound navigator on vertebral phantoms for posterior spinal surgery

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**Abstract:** Severe adolescent idiopathic scoliosis (AIS) requires surgery to halt curve progression. Accurate insertion of pedicle screws is important. This study reports a newly developed 3D ultrasound (3DUS) to localize pedicles intraoperatively and register a pre-op 3D vertebral model to the surface to be displayed for navigation. The objective was to determine speed of the custom 3DUS navigator and accuracy of pedicle probe placement. The developed 3DUS navigator integrated an ultrasound scanner with motion capture cameras. Two adolescent 3D printed spine models T2-T8 and T7-T11 were modified to include pedicle holes with known trajectory and be mounted on a high precision LEGO pegboard in a water bath for imaging. Calibration of the motion cameras and the 3DUS were conducted prior to the study. A total of 27 scans from T3 to T11 vertebrae with 3 individual scans were performed to validate the repeatability. Three accuracy tests that varied vertebral a) orientation, b) position and c) a combination of location and orientation were completed. Based on all experiments, the acquisition-to-display time was  $18.9 \pm 3.1$ s. The repeatability of the trajectory error and positional error were  $0.5 \pm 0.2^\circ$  and  $0.3 \pm 0.1$ mm, respectively. The a) center orientation, b) position and c) orientation/position on trajectory and positional error were for a)  $1.4 \pm 0.9^\circ$  and  $0.5 \pm 0.4$ mm, b)  $1.4 \pm 0.8^\circ$  and  $0.3 \pm 0.3$ mm and c)  $2.0 \pm 0.8^\circ$  and  $0.5 \pm 0.5$ mm, respectively. These results demonstrated that a high precision real-time 3DUS navigator for screw placement in scoliosis surgery is feasible. The next step will study the effect of surrounding soft tissues on navigation accuracy.

**Keywords:** 3D ultrasound navigator, Scoliosis Surgery, Repeatability, Pedicle screws insertion

## Introduction

Adolescent idiopathic scoliosis (AIS) is a 3-dimensional spinal condition that requires surgery in severe cases.[1] Surgery is undertaken to correct and prevent the curvature getting worse.[2] Posterior spinal fusion surgery with pedicle screws is the most common surgical approach. Based on the American College of Surgeons National Surgical Quality Improvement Program database, posterior fusion surgery for AIS was the second most common pediatric orthopedic surgery at 13.8%.[3] Screw insertion accuracy is important to prevent neurologic injury. Screw-related complication rates of 0.96% and spinal cord injury rates of 0.21% have been reported in the Scoliosis Research

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Society Morbidity and Mortality Database.[4] Pedicle screw breaches are typically measured in increments of 2 mm.[5]

Screws are usually inserted using free-hand methods, involving careful inspection of vertebral landmarks to ensure safe screw placement.[6] Image guidance techniques have grown in popularity, using fluoroscopy or computed tomography (CT) with navigation systems that track surgical tools using motion cameras, allowing internal vertebral anatomy to be visualized.[5] While these methods may reduce pedicle breaches, the increased ionizing radiation exposure for these adolescent patients, make these systems unfavorable for widespread usage.

Ultrasound is a non-ionizing imaging modality that has been used to quantify scoliotic curve severity in the past but has not been used for spinal navigation.[7,8] Ultrasound cannot penetrate past the posterior surface of the spine, but can produce high contrast images of the bony surface (Figure 1a). By combining motion capture position and orientation information with ultrasound images, the posterior surface of the vertebra can be reconstructed into a 3DUS surface (Figure 1b). Image registration can then be used to register a pre-operative CT or MRI image of the vertebra, to the localized 3D ultrasound surface image (Figure 1c). The 3D vertebral model that includes the vertebral internal anatomy can then be displayed on a navigation screen, alongside surgical tools, similar to a conventional navigation system (Figure 1d).

The goal of this study was to determine the accuracy of a custom 3D ultrasound navigation system and evaluate if the processing speed is fast enough to allow the system to be used in the surgical suite. The target accuracy is within 2mm and 5°, and the processing time is within 1 minute.

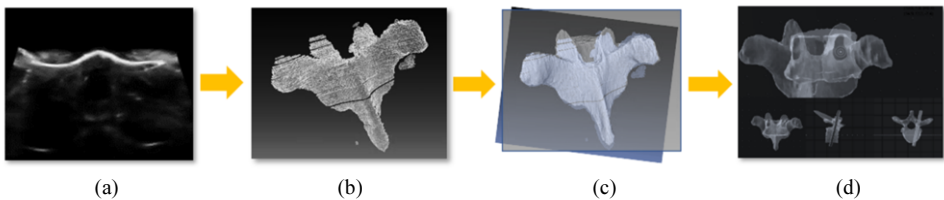


Figure 1. Schematic of 3D ultrasound navigation system (a) raw ultrasound image of vertebral surface, (b) 3D ultrasound surface reconstruction, (c) registered CT model overlaid on 3D ultrasound reconstruction, (d) navigation display

## Methods

A 3D ultrasound navigation system was developed by combining Optitrack Prime 13W cameras (NaturalPoint, Corvallis, OR, United States) with Ultrasonix SonixTablet (BK Ultrasound, Peabody, MA, United States) (Figure 2a). A high frequency linear transducer (38mm at 13.3 MHz) was used (Figure 2b). Motion capture markers were attached to the ultrasound transducer and was spatially and temporally calibrated using a wall phantom.[9] A custom ultrasound reconstruction and registration algorithm was developed in Matlab (Mathworks, Natick, MA, United States).[10-12] The reconstruction algorithm uses a pixel-based nearest neighbor method to place each pixel from the 2D ultrasound image in its 3D voxel position according to motion capture position and orientation. The position of each pixel relative to the motion capture coordinate system was recorded. Registration involved a two-step method. First, an intensity-based pre-registration was applied to pre-align the CT model and the captured

3D ultrasound surface, using the symmetry of the posterior surface of the spine along the sagittal plane. Second, an iterative closest point (ICP) algorithm was applied, where the closest points between two point-clouds are found and the appropriate translation and rotation matrix is calculated to register the points together. This process is iterated until the error is reduced to a certain threshold.

A navigation display was developed in Unity (Unity, San Francisco, California, USA) that allows placement of vertebrae in 3D space and is also compatible with Optitrack cameras to display surgical tools. The vertebra was placed in the Unity 3D environment according to the transformations found from the registration algorithm.

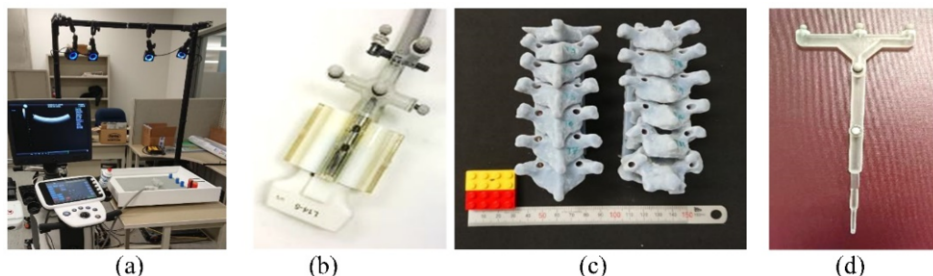


Figure 2. (a) Experimental setup including four overhead cameras (top) and ultrasound machine (left), (b) ultrasound transducer with attached capture markers, (c) vertebral phantoms, T3-T8 levels (left) and T7-T12 (right), (d) surgical probe with capture markers.

The 3D printed phantom was extracted and segmented from the CT scan of an adolescent patient and converted into a 3D model using Seg3D (Scientific Computing and Imaging Institute, Salt Lake City, Utah) (Figure 2c). Holes of known trajectory were added to the phantoms to allow insertion of a surgical probe (Figure 2d), to measure probe trajectory. A high precision Lego mount was also added to the vertebra to allow it to be mounted to a pegboard grid. The vertebra was submerged in water. Each vertebra from T3 to T11 was scanned three times at the capture volume origin to test repeatability (9 levels x 3 scans). Three randomized accuracy tests were conducted. First, the phantoms were placed at the volume origin and oriented in roll, pitch, and yaw to  $\pm 15^\circ$  and two vertebral levels were scanned twice each (24 scans). Next, the phantom was placed in neutral orientation at the corners of a 25.6cm x 12.8cm capture area and two vertebral levels were scanned twice each (16 scans). Lastly, orientations and positions were combined using a fractional factorial approach and vertebrae randomized amongst combinations resulting in each position being combined with three orientations and vertebrae (24 scans). To measure accuracy, the virtual probe was designed to have 0.5mm concentric rings. Positional accuracy was measured by placing the probe into the pedicle hole and measuring the amount of overlap between the multi-ringed probe with the hole. The trajectory error was calculated as the difference between the designed pedicle hole angles and the probe trajectory from motion capture cameras.

## Results and Discussion

Figure 3 presents the results from the repeatability study, showing an average positional repeatability of  $0.3 \pm 0.1$ mm and average trajectory repeatability of  $0.5 \pm 0.2^\circ$ , with the worst repeatabilities at 0.5mm and  $0.7^\circ$ . The repeatability of the ultrasound

system is in the submillimeter and subdegree range which would be important for a surgical navigation system.

Figure 4 presents the histograms of the entrypoint error and trajectory error from the three accuracy experiments. Table 1 shows the results from each of the experiments individually. All of the entrypoint and trajectory errors are within the 2mm and 5° target. However, there seemed to be decreased accuracies when combining orientation and position, particularly in trajectory error. The largest trajectory errors came from ultrasound scans that did not completely capture the full anatomy of the vertebral surface, resulting in poorer registrations. Furthermore, the scan time and processing time were 14.5±1.8s and 18.8±3.1s, respective. Hence the total time was 33.3±4.9s.

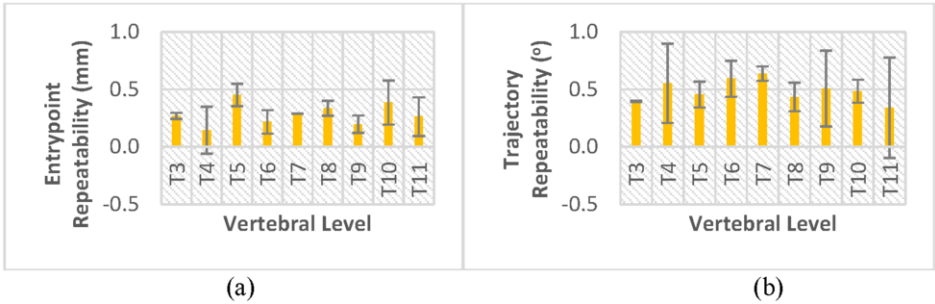


Figure 3. Repeatability in (a) entrypoint and (b) trajectory errors, according to vertebral level. Errors bars show standard deviations

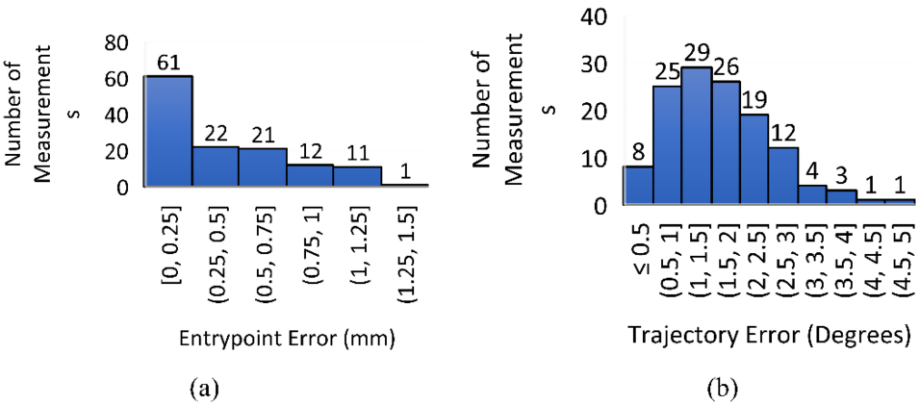


Figure 4. (a) Histogram of (a) entrypoint and (b) trajectory errors

Table 1: Errors from repeatability and accuracy tests

	Trajectory Error (degrees)	Positional Error (mm)
(A) Center-Orientation Test	1.4±0.9 (Range: 0.1-4.5)	0.5±0.4 (Range: 0.0-1.3)
(B) Position Test	1.4±0.8 (Range: 0.1-2.8)	0.3±0.3 (Range: 0.0-0.8)
(C) Orientation/ Position Test	2.0±0.8 (Range: 0.4-3.8)	0.5±0.5 (Range: 0.0-1.5)



Using 3D ultrasound is promising for navigation surgery. Previous ultrasound-CT registration achieved 0.66mm errors on a dry phantom in 2-3 minutes while conventional CT navigation has found surgical registration accuracies in the spine have been found to be close to  $1.3 \pm 0.1$ mm.[13,14] This current system is able to achieve better accuracies in less time. However, there remains a need to optimize image processing to ensure more consistent image registrations. Also, this study only used dry-bone phantoms, and so it did not include soft tissues which would more properly mimic surgical conditions. Future study will focus on further optimizing imaging properties and testing on a wider range of vertebrae with soft tissues.

## Conclusion and Significance

With accuracies of within  $0.4 \pm 0.4$ mm and  $1.5 \pm 0.9^\circ$ , ultrasound navigation seems to be a promising method of image guidance for spine surgery.

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# Validation of a novel handheld 3D ultrasound system for imaging scoliosis - phantom study

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**Abstract:** Use of 3D ultrasound (US) scanners to detect and monitor scoliosis have been validated. The Cobb angle, axial vertebral rotation, spinal flexibility, curvatures in the sagittal profile and the Cobb angle on the plane of maximum curvature (PMC) can be measured from coronal, transverse and sagittal planes of ultrasound images. However, traditional 3D ultrasound scanners are relatively bulky and expensive. 2D US handheld and low-cost scanners are widely available. To adapt the 2D scanners for scoliosis applications, a position and orientation system is integrated with the scanner. The objective of this study was to validate a newly developed 3D handheld US system to image the spine. The wireless handheld US scanner (C3-HD, Clarius, Canada) was selected because of its high resolution and availability of raw data. A wireless tracking system based on electromagnetic (G4 system, Polhemus, USA) was integrated with the Clarius ultrasound. During scanning, the ultrasound information was synchronized with the scanner's position and orientation by using custom developed software. Both information were streamed wirelessly to a laptop. Custom software reconstructed and displayed the 3D spinal image in real-time. A single 3D printed vertebra, two full plastic spine phantoms from T1-T12 vertebrae and a non-scoliotic volunteer were scanned. The 3D reconstruction process of a spine image was less than 3 seconds. The dimensional and the angle errors were 1 mm and 3°, respectively. This study demonstrated that a low-cost (\$11,000 USD) handheld 3D ultrasound system was developed and validated. Clinical trials on subjects attending will be the next step.

**Keywords:** 3D handheld ultrasound, High accuracy, High resolution, Fast reconstruction

## Introduction

Scoliosis is a 3D spinal curvature with vertebral rotation. It is usually detected between age ten and skeletal maturity. Approximately 3% of adolescents [1] have scoliosis and 80% of the cases are diagnosed as idiopathic. The Cobb angle is the current standard to diagnose, guide treatment decisions, monitor progression and quantify treatment outcome. Vertebral rotation is another feature used to evaluate scoliosis and influences treatment planning. Approximately 10% of adolescents with scoliosis require treatment [3, 4] such as bracing or extensive surgery. According to the information from the National Scoliosis Foundation,[5] approximately 6 million people in the United States have scoliosis and each year scoliosis patients make more than 600,000 visits to attend scoliosis clinics. Among these, 30,000 children receive brace treatment and

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38,000 undergo surgical intervention. According to Bunnell's study,[6] for patients with a Cobb angle between 20 and 30 degrees, the progression rate was only 20%.

Since there is no generally accepted method to predict which curves will progress, radiographs are routinely taken at each visit to monitor the curve. However, most of these radiographs show no clinically important progression and do not dictate a change in treatment. The radiographs taken for the non-progressive cases are, in retrospect, unnecessary. Unnecessary radiographs have a significant negative impact on patient wellbeing: the radiation dose received by a scoliosis patient during radiographic examination has been estimated at between 150  $\mu$ Sv [7] and 678  $\mu$ Sv.[8] On average, a 10 year-old child who is diagnosed with scoliosis may require 10 to 22 radiographs during the entire treatment period.[9, 10] The life-time risk of radiation is also more pronounced in growing children than in adults.

To minimize lifetime exposure to radiation, non-ionizing radiation methods such as surface topography and ultrasound (US) imaging have been investigated to determine if they can replicate the clinically relevant information from the radiograph.. Between these two methods, the US method is preferred as it can display the internal spinal alignment similar to radiography. According to Suzuki *et al.*[11] and Chen *et al.*[12] studies, the landmarks most accurately identifiable on US spine images were the spinous processes and laminae. Both of these landmarks have been used to measure the coronal curvature of the spine. Studies have demonstrated that identified the center of lamina (COL) to measure the coronal spinal curvature (proxy Cobb angle) and vertebral axial rotation (VAR) were accurate and reliable.[13, 14] Measurements of the proxy Cobb angle and VAR obtained from the US method or radiographs were within 3.8° and 5.0°, respectively [15-18]. The intra- and inter-rater reliabilities of the US measurements were high (ICC[2,1] > 0.83). Further studies demonstrated that using the aid of previous radiograph (AOR) with the US imaging method significantly improved the reliability and accuracy of the Cobb angle measurement. The mean absolute difference between the radiographic and US measurements was reduced to 2.8°. The ICC[2,1] values of the intra- and inter-observer reliabilities also improved to 0.95 and 0.91 for the AOR method,[18, 19] respectively. These promising measurement studies suggest that US imaging of AIS may allow for non-invasive monitoring of curve progression. In addition to the curvature measurements, researchers have used spinal flexibility information from the ultrasound imaging to assist in bracing and surgical treatment decisions.[20-23]

In general, a medical ultrasound unit is programmed for soft tissue applications and uses a proprietary data format which does not permit additional analysis of the raw data. Only the ultrasonic image can be exported for analysis. For the scoliosis application, each 2D image is stacked together to reconstruct a spine image for measurements. Position and orientation information are needed during data acquisition. Many low cost portable wireless ultrasound units are commercially available. The C3-HD (Clarius, Canada) unit was selected because of its low cost and high image resolution. To obtain the 3D position and orientation information, an electromagnetic wireless tracking system (G4, Polhemus) was used. Custom software was developed to integrate the US and position information together to generate spine images. The objective of this study was to investigate the accuracy and feasibility of using the developed system for scoliosis application.

## Methods

### a. Ultrasound Scanner

The C3-HD convex (Figure 1) handheld ultrasound scanner was selected for this study. This scanner operates at frequencies between 2-6MHz with 192 elements. The viewing angle is 73° with the penetration depth up to 40 cm. A key feature is the use of both Bluetooth and Wi-Fi Direct technologies to transmit wirelessly and display the images on smart devices. The device is also designed for ease of operation and delivers high quality images.



Figure 1. The Clarius C3-HD ultrasound scanner (164 x 78 x 38 mm and 392g)

### b. Electromagnetic Tracking System

The G4 system is a wireless motion tracking system that delivers full six degree of freedom and tracks both position and orientation. Position and orientation information is sent wirelessly to a smart device via a proprietary RF link. The system consists of a cube transmitter (10.34 cm x 10.29cm x 10.34 cm, 726g) which generates the electromagnetic field, a sensor (2.29cm x 2.82 cm x 1.52 cm, 9.1g) and a processing electronic unit (10.6 cm x 1.9 cm x 6.6 cm). A custom 3D printed holder was attached to the ultrasound scanner to secure the sensor at 12 cm from the scanner to prevent electromagnetic interference. The accuracy of the system was 0.5° RMS and 2mm RMS when the distance between the transmitter and the sensor was within 1 meter.

### c. Custom software

During the image acquisition, 2D US transverse view images were continuously transmitted from the scanner to a laptop via a wi-fi router. The corresponding location and orientation information of the frame was captured via the G4 RF-link. To make the 3D reconstruction process more reliable, 3 position points were digitized first by using the G4 system. Furthermore, to speed up the reconstruction process, the image area which was not related to vertebral column was cropped out. During reconstruction, the voxel nearest neighbor interpolation and maximum intensity projection volume rendering approaches were used.

### d. Experimental Study

Figure 2 show the developed system. Three experiments were performed in this study: a) a 3D printed single pediatric vertebra T7 was immersed into water and scanned by the developed system. The linear dimension of the single vertebra was measured by a tape (resolution 1mm) and on the ultrasound image 5 times. The difference between the measurements were reported. b) Two Sawbones full plastic spine phantoms from T1-T12 vertebrae were used to form a normal and a moderately scoliotic spine were immersed into a water tank and scanned by the developed system. Both spine phantoms were also scanned by a CT machine to obtain the reference image. The Cobb angle on PA view, the apical vertebral rotation and the Cobb angle on the plane of maximum deformity were measured from both types of images. c) a volunteer with no scoliosis was

scanned by the original ultrasonix machine and the new integrated device. He was requested to stand in a standard posture in a positioning frame in our scoliosis clinic. The images from both systems were compared.



Figure 2. The developed 3D portable wireless handheld ultrasound system.

Results and Discussion

Table 1 shows a summary of the results from the experiment a. By measuring both the phantom and images 5 times, the average maximum linear dimensional error was  $1.0\pm0.1\text{mm}$ . Table 2 shows the results from experiment b. The maximum difference between the measurements from the CT images and US images were  $3^\circ$ . This value was within the clinical acceptable difference. Fig 3a shows the operator scans on a volunteer, and (b) and (c) are the reconstructed US spine images from the new device and the original Ultrasonix machine, respectively. The image quality looks pretty similar, but the reconstruction time on the new device using the laptop (i7 Intel Core, 32GB RAM, 8GB Nvidia RTX 2070) took 3 seconds comparing with the original Ultrasonix system took 1 minute. The new device was able to use the GPU capability to reconstruct the image faster. For the volunteer who had no scoliosis, the curvature angle measured from both images was  $0^\circ$ .

Furthermore, the cost of the new device was US \$11,000, compared to the original Ultrasonix system was US \$45,000.

Table 1. A summary of the linear dimension error

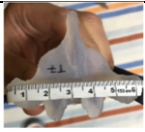
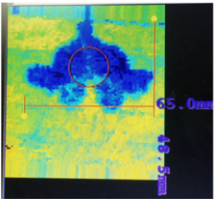

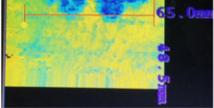

	Phantom Measurement (mm) (n = 5)	Image Measurement (mm) (n = 5)	Differences (mm)
Horizontal distance between the tip of the transverse processes	 64.0±0.5	65.0±0.2 	1.0±0.1
Vertical distance from the tip of spinous process to the end of the inferior articular process	 49.0±0.3	48.5±0.2 	0.5±0.1

Table 2. A summary of the angle measurements differences from both CT and US images.

	Curved Spine		Straight Spine		
	CT image	US Image	CT Image	US Image	
Apical VR	18°	21°	2°	2°	
PA Cobb	48°	46°	6°	5°	
PMC Cobb	51°	48°	9°	6°	

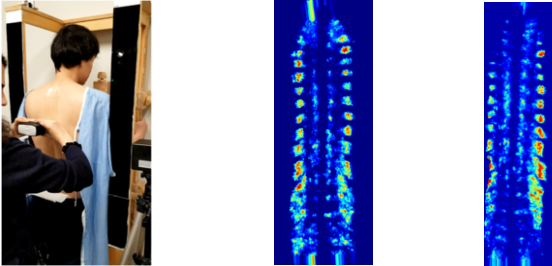


Figure 3. (a) scanning on the volunteer (b) using the new device (c) original Ultrasonix system

Conclusion and Significance

A low-cost (\$11,000 USD) handheld 3D ultrasound system was developed which demonstrated a promising proof of concept. Clinical trials will be conducted to further validate the system.

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# Using ultrasound for screening scoliosis to reduce unnecessary radiographic radiation - a prospective diagnostic accuracy study on 442 schoolchildren

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**Abstract:** Scoliosis screening is important for timely initiation of brace treatment to mitigate curve progression in skeletally immature children. Scoliosis screening programs frequently include the protocol of referring children screened positive with Scoliometer and Moiré Topography for confirmatory standard radiography. Despite being highly sensitive (88%) for detecting those who require specialist referral, the screening program was found to have more than 50% false positive rate that leads to unnecessary radiation exposure. Radiation-free ultrasound has been reported to be reliable for quantitative assessment of scoliosis curves. The aim of this prospective diagnostic accuracy study was to determine the accuracy of ultrasound in determining the referral status for children initially screened positive for scoliosis. 442 schoolchildren with a mean Cobb angle of  $14.0 \pm 6.6^\circ$  were recruited. Using x-ray as the gold standard, the sensitivity and specificity of ultrasound in predicting the correct referral status were 92.3% and 51.6% respectively. ROC curve analysis revealed an area under curve of 0.735 for ultrasound alone and 0.832 for ultrasound plus scoliometer measurement. The finding provided strong evidences on the accuracy of ultrasound in determining the referral status that could result in more than 50% reduction of unnecessary radiation exposure for children undergoing scoliosis screening.

**Keywords:** Ultrasound, screening, scoliosis, prospective diagnostic accuracy study

## Introduction

In the governmental scoliosis screening program in Hong Kong, schoolchildren screened positive with Adam's Forward Bending Test and Moiré Topography are referred for confirmatory radiographic assessment. Subjects with Cobb angle  $\geq 20^\circ$  are

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referred for specialist care. There are cases screened positive and referred for x-ray investigation but noted to have Cobb angle  $< 20^\circ$  thus being subjected to unnecessary x-ray exposure. This study aimed to evaluate (1) the sensitivity and specificity of ultrasound in identifying schoolchildren who require “specialist referral” (i.e. with radiological Cobb angles  $\geq 20^\circ$ ); and (2) whether incorporation of angle of trunk rotation (ATR) measured with a Scoliometer can improve the accuracy of ultrasound assessment.

## Methods

This was a prospective diagnostic accuracy study. 442 schoolchildren screened positive for suspected scoliosis were recruited from the scoliosis screening program. In addition to standing posteroanterior whole spine EOS radiographs, ultrasound assessment of the spine from L5 up to T1 vertebrae was independently done on the same day. Automatic spinous process angles (SPA) were obtained from the ultrasound volume projection images (VPI) (Figure 1). X-ray-based referral status, i.e. “Cobb $\geq 20^\circ$ -for specialist referral” or “Cobb $<20^\circ$ -not for specialist referral”, was the gold standard. The ultrasound-based referral status was determined with the ultrasound spinous process angle (SPA). ATR was also measured.

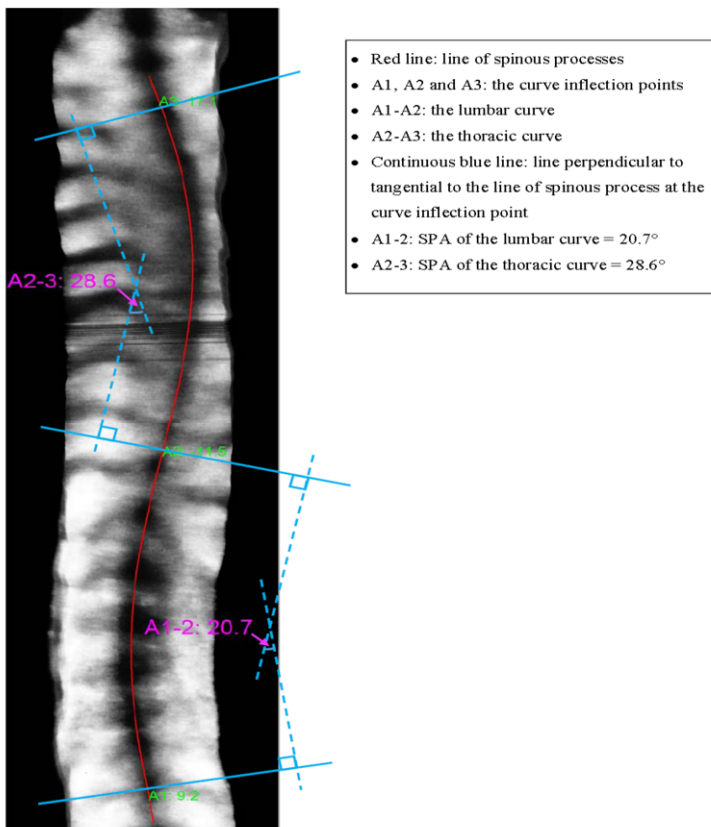


Figure 1. A volume projection image of the spine showing the line of spinous processes with which the Spinous Process Angle (SPA) can be measured.

## **Results and Discussion**

243 females and 199 males (mean age  $13.2 \pm 1.8$  years) with various degrees of coronal curvatures (mean Cobb angle of major curve  $14.0^\circ \pm 6.6^\circ$ ) were studied. 78 subjects (17.6%) had Cobb angles  $\geq 20^\circ$ . Patient-based analysis showed that area under the ROC curve was 0.735 ( $p < 0.001$ ) with ultrasound-derived SPA alone for predicting the referral status, and improved to 0.832 ( $p < 0.001$ ) when ATR was incorporated into the prediction model. The sensitivity and specificity were 92.3% and 51.6% respectively whereas the positive and negative predictive values were 29.0% and 96.9% respectively. In addition, the positive likelihood ratio was 1.91, while the negative likelihood ratio was 0.15.

## **Conclusion and Significance**

This study provided strong evidences that ultrasound together with ATR measurement was useful for identifying schoolchildren who did not require specialist referral with Cobb angle  $< 20^\circ$ . Ultrasound could therefore be considered for incorporation into the scoliosis screening program for minimizing radiographic exposure.

**Acknowledgement:** This study is supported by Health and Medical Research Fund of the Hong Kong S.A.R., China (Project no: 04152896)

# Is ultrasound accurate for radiation-free quantitative assessment of spinal curvatures in patients with idiopathic scoliosis – a systematic review and meta-analysis

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**Abstract:** Despite application of ultrasound for quantitative measurement of spinal curvatures has been reported with various studies, a systematic review for such is lacking. This systematic review aimed to evaluate (1) reliability of ultrasound; (2) validity of ultrasound using radiographic measurement as gold standard in idiopathic scoliosis patients; and (3) the use of various anatomical landmarks for measurement of spinal curvatures. MEDLINE, EMBASE, CINAHL, and CENTRAL databases were searched. QUADAS-2 quality assessment tool was adopted. Reliability of ultrasound in terms of intra-class correlation coefficient was recorded. Pearson correlation coefficients between ultrasound and radiographic measurements were extracted for meta-analysis. Subgroup analyses based on ultrasound measurement protocols of spinous process (SP), transverse processes (TP) and center of lamina (COL) were conducted. Eleven articles reporting 18 correlation analyses on 766 subjects were eligible for meta-analysis. The mean inter-rater reliability of ultrasound measurement was  $0.87 \pm 0.07$ . Pooled correlation for all studies was 0.918 (95% CI: 0.868-0.949), exhibiting substantial heterogeneity ( $I^2=90.50\%$ ,  $p<0.001$ ). Subgroup analyses showed that pooled correlations were 0.887 for COL method (comprising 356 subjects); 0.924 for SP method (255 subjects); and 0.941 for TP method (117 subjects); all with notable heterogeneity ( $I^2>90\%$ ,  $p<0.001$ ). The overall risk of bias was rated moderate; yet publication bias was noted. Evidences showed that ultrasound was a promising non-invasive method with satisfactory validity and reliability for measuring coronal curvatures utilizing the SP, TP or COL methods. Further development of three-dimensional ultrasound towards scoliosis assessment will facilitate its translational application for managing scoliosis.

**Keywords:** ultrasound, scoliosis, deformity, systematic review

## Introduction

Despite application of ultrasound for quantitative measurement of spinal curvatures in scoliosis has been reported with multiple studies, a systematic review on the accuracy of ultrasound remains lacking in the literature.

This systematic review aimed to evaluate (1) reliability of ultrasound; (2) validity of ultrasound using radiographic measurement as gold standard in idiopathic scoliosis patients; and (3) the use of various anatomical landmarks for measurement of spinal curvatures.

## Methods

The systematic review was conducted following the guideline of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA checklist).[1] Relevant studies that involved ultrasound imaging for quantitative assessment of the spine were searched from four databases, namely the MEDLINE, EMBASE, CINAHL, and Cochrane Library (CENTRAL) databases.

Articles were included if they met the following criteria:

- (1) Report on the correlation between ultrasound (index test) and radiographic (reference standard) measurement of spinal curvatures in patients with idiopathic scoliosis (IS)
- (2) Publication as a full paper in a peer-reviewed scientific journal

The exclusion criteria were:

- (1) *In vitro* experiments or pilot studies involving less than 10 scoliosis patients
- (2) Articles without sufficient information for calculation of correlation coefficient between ultrasound and radiographic measurements
- (3) Non-idiopathic scoliosis subjects
- (4) Application of ultrasound other than quantification of spinal curvatures, for example, muscle quantification, skeletal maturity assessment, bone quality measurement, spinal flexibility measurement, brace casting, orthotic design, surgical related procedures like anesthesia, operative guidance, or imaging for magnetically controlled growing rods
- (5) Review articles, editorials, letters, comments, case reports, or conference abstracts
- (6) Non-English studies

The search was up to 22-October-2018. QUADAS-2 quality assessment tool was adopted. The intra- and inter-rater reliability of ultrasound measurement in terms of intra-class correlation coefficient (ICC) was recorded. If more than one ICC values were reported for different raters or per different scans in the articles, the lowest value was documented. The ICC value was characterized as very reliable (0.80-1.00), moderately reliable (0.60-0.79), and questionably reliable (less than 0.60) according to the Currier criteria.[2]

The validity of ultrasound spinal measurement was evaluated using radiography as the gold standard. The Pearson correlation coefficient ( $r$ ) values between ultrasound and radiographic measurement were extracted from each study and reanalyzed to obtain the pooled correlation and 95% confidence intervals (CIs) using the random effects model of meta-analysis. If more than one correlation coefficient values were reported for

various curve location (as upper thoracic, main thoracic, thoracolumbar, or lumbar region) in the articles, the overall correlation was chosen for meta-analysis. The correlation coefficient was characterized as very good to excellent correlation (0.75-1.00), moderate to good correlation (0.50 to less than 0.75), or poor correlation (0.25 to less than 0.50).[3]

The heterogeneity of the correlation results across studies was tested by the inconsistency index ( $I^2$ ), of which p-value of  $<0.05$  or  $I^2$  of  $>50\%$  indicated notable heterogeneity.[4] Subgroup analysis was performed to investigate the potential heterogeneity by stratifying studies according to the ultrasound measurement protocols adopted, namely spinous process (SP) method, transverse processes (TP) method, and center of lamina (COL) method. In addition, the presence of publication bias and selection bias was visually assessed using the funnel plot. Symmetry of the funnel plot indicated absence of publication bias; while 95% of the studies lie within the funnel defined by the two diagonal lines that represented the 95% confidence limits (effect $\pm$ 1.96 SE) around the summary effect for each standard error on the vertical axis indicated absence of selection bias.[5]

Review Manager (RevMan) Computer Program Version 5.3 (Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2014) and the MedCalc Statistical Software version 18.11.3 (MedCalc Software bvba, Ostend, Belgium; <https://www.medcalc.org>; 2019) were used for the meta-analysis.  $p<0.05$  was considered statistically significant.

## Results and Discussion

After screening 574 articles retrieved from literature search, eleven articles reporting 18 correlation analyses on 766 subjects were noted to be eligible for inclusion in this systematic review. The mean inter-rater reliability of ultrasound measurement was  $0.87\pm0.07$ . Pooled correlation for all studies was 0.918 (95% CI: 0.868-0.949), exhibiting substantial heterogeneity ( $I^2=90.50\%$ ,  $p<0.001$ ). Subgroup analyses showed that pooled correlations were 0.887 for the COL protocol (comprising 356 subjects); 0.924 for the SP protocol (255 subjects); and 0.941 for the TP protocol (117 subjects); all with notable heterogeneity ( $I^2>90\%$ ,  $p<0.001$ ). The overall risk of bias was rated moderate; yet publication bias was noted.

## Conclusion and Significance

Evidences showed that ultrasound was a promising non-invasive method with satisfactory validity and reliability for measuring coronal curvatures utilizing the SP, TP or COL protocol. Further development of three-dimensional ultrasound towards scoliosis assessment will facilitate its translational application for managing scoliosis.

This study is supported by Health and Medical Research Fund of the Hong Kong S.A.R., China (Project no: 04152896)

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# Chapter 6

## Biomechanics, Movement, and Posture

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# The effect of scoliosis support orthosis bracing on adult spinal deformity patients: evaluation of gait and dynamic balance

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**Abstract:** Non-operative treatment is regarded as the first-line therapy for patients with adult spinal deformity (ASD) without neurologic deficits or significant impairment. While there is high-level evidence supporting the use of rigid bracing in adolescent idiopathic scoliosis, there is a paucity of literature pertaining to the use of scoliosis support orthosis (SSO) in ASD patients. To investigate the impact of an SSO on pain, gait parameters, and functional balance measures in symptomatic ASD patients. Thirty ASD patients (26 Females, Age: 72.7, Cobb Angle: 47.1°) were evaluated on 3 different occasions: first day of bracing: baseline (Pre), and 45-min post fitting (Post45m), and after 8-weeks of bracing for 4 hours a day (Post8w). Each patient performed a 6-minute walk (over-ground gait), a dynamic balance test, and completed VAS, ODI, and SRS22r. Significant short- and long-term improvements using SSO were found in the 6-minute walk (Pre: 278.6; Post45m: 322.2; Post8w: 338.8 m,  $p<0.001$ ), walking speed (Pre: 0.88; Post45m: 0.97; Post8w: 0.97 m/s,  $p<0.001$ ), head total sway distance during the balance test (Pre: 81.33; Post45m: 68.63; Post8w: 60.72 cm,  $p=0.048$ ), low-back pain (VAS: Pre: 5.5; Post45m: 3.5; Post8w: 3.3,  $p<0.001$ ), and for the ODI (Pre: 41.9; Post45m: 32.9; Post8w: 30.1,  $p=0.005$ ). This study demonstrated clinically significant improvements in PROMs, spatiotemporal gait measures, and functional balance measures after continuous use of a SSO. These improvements were observed immediately following brace-fitting and maintained at an 8-week follow-up. Given these results, it is reasonable to consider a SSO for conservative management of patients with mild symptoms of pain and deformity, and who have not yet progressed to meet surgical indications.

**Keywords:** Scoliosis Support Orthosis; Spinal Bracing; Adult Spinal Deformity; Non-Operative Treatment; Gait Analysis.

## Introduction

Non-operative treatment is regarded as the first-line of therapy for patients with ASD without neurologic deficits or significant impairment.[1-5] Traditional conservative management modalities consist of physical therapy, heat, stretching, and aerobic exercise programs. While bracing is an accepted conservative treatment option, it is rarely prescribed because its efficacy in reducing pain in these patients has not been established and because bracing is not well tolerated by adults.[3,6,7] While there is high-level

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evidence supporting the use of body jacket style rigid bracing in adolescent idiopathic scoliosis (AIS),[8,9] there is a paucity of literature pertaining to the use of scoliosis support orthosis (SSO) in ASD patients. The goal of bracing in AIS is to modulate growth and limit curve progression. The flexibility and continued growth of adolescent spines serve as the basis for brace therapy in this population. Conversely, adult spines, particularly ones with deformity, are stiff and thus less responsive to external force.[10] As a result, brace treatment of ASD focuses on achieving better physiologic alignment and relieving the pain related to postural deformity and segmental collapse.[11]

More recent efforts have focused on assessing ASD patients through objective dynamic gait and balance testing. Haddas et al. have used 3-dimensional kinematic testing to further evaluate gait and balance in ASD.[12-14] When compared with healthy controls, ASD patients exhibited significantly slower gait speed, decrease in step length, cadence, longer stride time, stance time, double support time, and an increase in step width.[12] Furthermore, they also demonstrated that ASD patients had altered muscle efforts resulting in an inefficient gait pattern with higher energy demands even in ambulation with assistive devices.[15,16] Subsequent studies focused on quantifying balance and defining the cone of economy dimensions for ASD patients.[13,14] ASD patients were found to expend more energy during a simple standing task in an effort to maintain balance within their cone of economy when compared with healthy controls.[13]

Prior studies provide little to no information on the impact of bracing on gait parameters or functional balance measures in ASD patients.[11] Therefore, the purpose of this study was to investigate the impact of a new style of SSO on pain, gait parameters and functional balance measures in symptomatic ASD patients.

## **Methods**

Thirty ASD patients were evaluated twice on the first day of bracing (baseline and 45 minutes post SSO fitting; Post45m), and a second time 8±2 weeks post-brace fitting (Post8w). For data acquisition, subjects were fitted with 41 external reflective markers based on those validated and published in the literature.[17,18]

Each patient performed a series of functional and clinical tests at each assessment time point. First, 5 acceptable over-ground gait trials at self-selected speeds were performed where each patient walked 10 meters, stepping on three force platforms embedded on a leveled walkway. For the dynamic balance test, patients stood with their eyes open for 60 seconds (modified Romberg test) with one foot each on the force platforms. Patients then performed a standardized 6-minute walk test and Time Up and Go test (TUG).[19,20] These physical function measures have been previously employed to assess ASD patients.[21] The TUG measures functional mobility by having the patient, as quickly as possible, rise from a chair without support, walk 3 meters, turn around, walk back to the chair and sit down.[22] The 6-minute walk test assesses distance walked over 6 minutes as a sub-maximal test of endurance when the patients may take as many standing rests as they like.

Prior to each evaluation, patients were asked to complete the ODI (version 2.1.a) and a visual analog scale (VAS) to assess back and leg pain intensity, SRS-22r, Fear Avoidance Beliefs Questionnaire (FABQ),[23] and Tampa Scale for Kinesiophobia (TSK).[24,25] After completion of the baseline pain and functional testing, each patient was fitted with an identical off-the-shelf SSO (Peak™ Scoliosis Brace, Aspen Medical Products, Irvine, CA, USA) consisting of an inelastic fabric belt coupled to a rigid lateral strut that was

adjusted by a trained clinician. After 45 minutes of wearing the SSO, all previously described functional and clinical tests were repeated while the patients were wearing the SSO. Patients were instructed to wear the brace from 4 to 8 waking hours per day. Brace wear compliance was recorded with an average of 4.5 hours per day. No formal physical therapy was carried out during the study period. Follow-up tests were performed after 8 weeks of continued use of SSO as prescribed. During this testing the patients were not wearing the brace. Three-dimensional (3D) kinematic data was recorded at 120Hz via a motion capture system (Vicon, Oxford, UK) for the functional tests of over-ground walking and standing balance. Spatiotemporal variables were calculated for the 10 m walk test. Sway calculation for the Romberg's test was based on previously published balance work.[26] Data was analyzed with a repeated measurement analysis of variance (RM-ANOVA) to determine differences between pre- and post-bracing measurements for each of the outcome variables.

## Results and Discussion

A total of 30 patients were included in our analysis (26 Females, Age:  $72.7 \pm 4.5$  years, Height:  $1.58 \pm 0.1$  m, Weight:  $67.7 \pm 16.1$  kg, BMI:  $26.9 \pm 5.2$ , Cobb Angle:  $47.1 \pm 21.2^\circ$ ). Due to the COVID-19 pandemic, we were unable to complete post 8-week assessments for 2 patients. No adverse events related to brace wear were reported.

### *Short-Term Effect (45 minutes after SSO fitting):*

Analysis of the PROMs verified significant short-term improvements in the pain as observed from reduced VAS for low-back (Pre: 5.5 cm vs. Post45m: 3.5 cm,  $p < 0.001$ ), and leg pain (Pre: 3.7 cm vs. Post45m: 1.6 cm,  $p = 0.001$ ). Improvement were also observed for scores from ODI (Pre: 41.9 vs. Post45m: 32.9,  $p = 0.005$ ), SRS22r Function (Pre: 2.9 vs. Post45m: 3.1,  $p = 0.005$ ), SRS22r Pain (Pre: 2.5 vs. Post45m: 2.7,  $p = 0.009$ ), SRS22r Satisfaction (Pre: 2.6 vs. Post45m: 3.0,  $p = 0.017$ ), and SRS22r Total score (Pre: 2.8 vs. Post45m: 3.0,  $p = 0.033$ ). Analysis of the gait parameters verified significant short-term improvements in the 6-minute walk (Pre: 278.6 vs. Post45m: 322.2 m,  $p < 0.001$ ), TUG (Pre: 12.4 vs. Post45m: 10.9 s,  $p < 0.001$ ), walking speed (Pre: 0.88 vs. Post45m: 0.97 m/s,  $p < 0.001$ ), step time (Pre: 0.58 vs. Post45m: 0.55 s,  $p = 0.001$ ), stance time (Pre: 0.75 vs. Post45m: 0.71 s,  $p < 0.001$ ), swing time (Pre: 0.41 vs. Post8w: 0.39 s,  $p = 0.004$ ), and double support time (Pre: 0.17 vs. Post45m: 0.16 s,  $p = 0.022$ ). Analysis of the functional balance measures using CoE parameters verified significant short-term improvements in CoM (Pre: 47.70 vs. Post45m: 37.26 cm,  $p = 0.046$ ) and head (Pre: 81.33 vs. Post45m: 68.63 cm,  $p = 0.048$ ) total sway distance (TSD)

### *Long-Term Effects (8 weeks):*

Significant long-term improvements were observed on PROMs. Pain as reported on VAS reduced for low-back overall (Pre: 5.5 cm vs. Post8w: 3.3 cm,  $p = 0.009$ ), low-back in the past 24 hours (Pre: 5.8 cm vs. Post8w: 4.0 cm,  $p = 0.033$ ), and, low-back in the past week (Pre: 6.1 cm vs. Post8w: 4.3 cm,  $p = 0.013$ ). stability scores and patient satisfactions improved as noted by scores from questionnaires: ODI (Pre: 41.9 vs. Post8w: 30.1,  $p = 0.004$ ), SRS22r Pain (Pre: 2.5 vs. Post8w: 2.8,  $p = 0.006$ ), SRS22r Satisfaction (Pre: 2.6

vs. Post8w: 3.3,  $p=0.005$ ), SRS22r Total score (Pre: 2.8 vs. Post8w: 3.1,  $p=0.019$ ), and TSK (Pre:32.2 vs. Post8w: 24.5,  $p=0.023$ ). Long-term improvements were also observed for spatiotemporal gait measures: 6-minute walk distance increased (Pre:278.6 vs. Post8w: 338.8 m,  $p<0.001$ ), TUG time reduced (Pre:12.4 vs. Post8w: 9.9 s,  $p<0.001$ ), walking speed increased (Pre:0.88 vs. Post8w: 0.97 m/s,  $p=0.009$ ), step time reduced (Pre:0.58 vs. Post8w: 0.55 s,  $p=0.003$ ), stance time reduced (Pre:0.75 vs. Post8w: 0.71 s,  $p=0.010$ ), swing time decreased (Pre: 0.41 vs. Post8w: 0.39 s,  $p=0.009$ ), and double support time reduced (Pre: 0.17 vs. Post8w: 0.16 s,  $p<0.001$ ) after 8-weeks of conservative management. Analysis of the CoE parameters verified significant long-term improvements in sway of CoM (Pre: 47.70 vs. Post8w: 36.16 cm,  $p=0.018$ ) and head (Pre: 81.33 vs. Post8w: 60.72 cm,  $p=0.010$ ) TSD, and head coronal RoS (Pre: 4.19 vs. Post8w: 3.22 cm,  $p=0.038$ ).

Low back pain was significantly reduced compared with baseline after 45 minutes of brace wear and was maintained at 8 weeks follow-up. At 8-week follow-up, patients noted that their back pain in the preceding 24 hours and 7 days was also significantly improved compared with baseline. Leg pain was also significantly reduced at 45 minutes and 8 weeks. ODI, a measure of disability due to low back pain, was significantly reduced at both 45 minute and 8-week time points. The function domain of the SRS22r was significantly improved after brace fitting. Improvement in the pain and satisfaction domains were evident at first follow-up and were maintained through the study period. The TSK score, which is known to correlate with biomechanical measures of function,[24] also improved at final follow-up compared with baseline assessment.

Improvements in step time, stance time, swing time and double-support time were evident after 45 minutes of SSO wear and maintained at final follow-up. Patients had significant improvements in the 6-minute walk test and TUG at immediate and 8-week follow-up. Furthermore, there was additional significant improvement for the TUG in between the assessments. Patients also had improved balance measures following brace fitting with reduced TSD for the CoM and head. While only head coronal RoS was significantly reduced, all CoE measures were reduced immediately after SSO fitting and at final follow-up. The ASD patients in our study had significant improvements in gait parameters and functional balance measures immediately after being fitted with an SSO and these improvements were maintained at final follow-up. These results support good ambulatory balance, increased independence, paired with less pain which essentially improves the quality of life in ASD patients using the SSO.

There is a lack of standardization and protocols for nonoperative treatment for ASD[27,28] and the role of an SSO in the ASD treatment algorithm has yet to be defined. Authors have pointed to an improved quality of life outcomes following surgery for ASD compared with non-operative management.[27-29] However, these results alone do not preclude the use of an SSO in the treatment of ASD. Patients in this study were not deemed to be candidates for surgery based on their function, disability and neurological status. Nevertheless, they experienced significant improvement across both clinical and functional measures. Given these results, it is reasonable to consider SSO treatment for patients with more mild scoliosis based disabilities not at the point of surgical intervention.

SSO treatment may also have a role in patients who are deemed to be surgical candidates. Patients in this study had an average baseline ODI of 41.9 and SRS-22r score of 2.8, which are comparable to surgical patients in a recent randomized clinical trial.[27] A considerable number of patients experience complications following surgical correction of ASD.[27,28,30] As a result, some patients opt for non-operative care despite being offered surgery. In light of the documented limitations of current non-operative care, which has not included bracing, for these patients an SSO may be helpful. Furthermore, an SSO

may be useful for patients that require medical optimization prior to ASD surgery. For example, many patients undergo pharmacologic treatment of osteoporosis in the months prior to surgery in an effort to reduce complications and improve outcomes.[31-33] Brace treatment during this period may reduce pain and decompensation in the time prior to surgery.[34]

There are a number of limitations to the current study. While this study is strengthened by its prospective design, manufacturer support is acknowledged as a potential source of bias. Two patients missed their final follow-up appointment due to the COVID-19 pandemic, potentially reducing the statistical power of the results. Follow-up greater than 8 weeks is needed to fully assess the utility of SSO treatment. Nevertheless, over 93% patient compliance for an 8-week follow-up is a strength and adds to the potential benefit of using SSO as an effective non operative treatment option. The majority of the patients in this study are female. However, the proportion of female patients is nearly identical to that reported in a recent randomized clinical trial of ASD patients.[27] In light of this and our study design (consecutive patients), the authors consider the reported cohort to be reflective of a typical ASD practice. As is common in studies of this nature,[11] the lack of a control cohort and compliance measures are limitations. Furthermore, ASD represents a heterogeneous group of disorders and includes unique patient populations defined by their deformity morphology. Further work is needed to identify more precise patient populations, if any, who would benefit from SSO treatment.

## Conclusion and Significance

In conclusion, we demonstrated clinically significant improvements in PROMs, spatiotemporal gait parameters and functional balance measures with the use of a SSO for patients with ASD. Some improvements were established immediately following brace fitting and many improvements were observed after wearing SSO for 8 weeks. In addition, this is the first SSO study for ASD to examine gait parameters and functional balance measures in order to understand the benefits of non-operative treatment from a functional and activity of daily living perspective. Based on the results of this study, it is reasonable to consider custom fitted SSO as a treatment option to provide a measurable degree of pain relief and improvement of function for patients with ASD, if the goals of treatment match the measured benefits demonstrated in our paper. Future studies are warranted to investigate if the observed benefits can be maintained over longer periods, possibly with reduced wear times for patients with ASD.

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# Effect of PSSE on postural sway in AIS using center of pressure

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**Abstract:** We haven't known whether the center of pressure (COP) could be considered as a better indicator in the evaluation of posture and balance change after the physiotherapeutic scoliosis specific exercise (PSSE) during level walking. The objective of this study was: 1) to determine changes in COP displacement in anterior-posterior (COP-AP) and medial-lateral (COP-ML) for AIS following the PSSE; 2) to find out COP oscillation (COP-OS) from the midline for the left and right foot; 3) to investigate max pressure at the forefoot, midfoot and hindfoot bilaterally. AIS patients with three reflective markers on their back walked on the pressure sensors embedded treadmill at 2 km/h and their trunks were also registered by DIERS Formetric 4D system. Each child received the PSSE for 12 weeks by the same physical therapist and had a dynamic pressure analysis before and after the PSSE. Six AIS children at a mean age of 13 years and with averaged major Cobb angle of 26° were enrolled. There was an increase in COP-AP (15%) and a decrease in the COP-ML (-25%) following the PSSE. COP-OS on the left foot shifted farther away from the midline (about 16%) as the right side moved closer (-1%), which becomes more symmetrical (Pre-PSSE: 0.86mm & Post-PSSE: 0.32mm). There were increased pressures on the left (35%) and right (26%) hallux after PSSE. Pressure metrics, especially including COP-ML, COP-AP, COP-OS, and peak pressures on the forefoot, may be opted as optimal predictors to posture improvements by the means of PSSE.

**Keywords:** PSSE, AIS, Center of Pressure (COP), Posture

## Introduction

There have been few studies published looking at balance and posture in adolescents with idiopathic scoliosis (AIS) using both static and dynamic pressure analysis. Current literature suggests individuals with adolescent idiopathic scoliosis have a postural deviation from midline affecting everyday walking.[1] AIS has the most deviated center of pressure trajectory in the medial-lateral direction at the mid-foot. However, it is unknown whether center of pressure (COP) could be considered a better indicator in the evaluation of posture and balance change after physiotherapeutic scoliosis specific exercise (PSSE) intervention during level walking.

There is little evidence on whether physiotherapy intervention in the form of PSSE influences change in COP. Center of pressure is the location at which the instantaneous vector of the ground reaction force acts when the plantar surface of the foot contacts the

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ground during gait. This 2-dimensional parameter is ever changing with each step and becomes an insightful measurement when determining differences in gait patterns in the AIS population.

The North American conservative standard of care for adolescent idiopathic scoliosis solely relies on observation and bracing, while other countries are more inclusive of exercise intervention as part of their standard of care. According to Schreiber et al. differences between North American and European guidelines are partly due to “cost, culture, social standards, or, possibly differing appraisals of the quality of research involving exercise”.[2] The most impressionable time for conservative treatment is during a child’s growing years; more specifically the adolescent years.

When comparing PSSE to Schroth Method and spine stabilization exercises, one treatment method is not necessarily superior to the other. Past literature looked at the effects of stretching, Schroth and strengthening exercises over an eight-week course and saw a decrease in Cobb angle and rib hump post PSSE,[2-5] but COP changes due to physiotherapeutic intervention has yet to be investigated.

The objective of this study was: 1) to determine changes in COP displacement in anterior-posterior (COP-AP) and COP-ML for AIS following the PSSE; 2) to find out COP oscillation(COP-OS) from the midline for the left and right foot; 3) to investigate the changes of max pressure at the forefoot, midfoot and hindfoot bilaterally.

## **Methods**

This retrospective study was approved by the Institutional Review Board at Children’s Wisconsin. Participants were adolescents (between 10-18 years of age), with a Cobb angle >10 degrees, Risser stage of 0-5, with no prior physiotherapy treatment. Six participants with a mean age of 13 years and with an average major Cobb angle of 26 degrees were enrolled. Each child was seen through Children’s Wisconsin Scoliosis Clinic and received the standard of care – radiograph images on EOS and brace recommendation based on curve type and risk of progression. Participants received PSSE for 12 weeks by the same physiotherapist and had a dynamic pressure analysis performed before and after the 12 weeks. The therapist was blinded to the initial pressure analysis report, and therefore the course of treatment was not influenced by the findings.

The patients were seen in the Musculoskeletal Functional Analysis Center at Children’s Wisconsin. The Diers Formetric 4D (DIERS Formetric 4D system, Diers Medical Systems, Chicago, IL) was used and three reflective markers were placed on the posterior trunk of the patient: vertebral prominence (VP) at T1, left sacral dimple (DL) and right sacral dimple (DR).

The DIERS system collects data using a light-optical scanning method based on Video-Raster-Stereography (VRS) along with two force plates embedded in the treadmill (one on each side of the midline). Two cameras record from the back, one in line with the waist and the second from above (Figure 1). Data is collected by having the system project a line grid on the posterior aspect of the patient using the three reflective markers as reference points while the patient walks on the treadmill at a speed of 2 km/h. Within 15 seconds in which they walk, there must be at least 3 steps on each side of the treadmill in order to achieve sufficient, quality data. Overall, four pressure matrix were registered, including the COP-AP, COP-ML, COP-OS, and peak pressures at the forefoot, midfoot, and hindfoot bilaterally. A descriptive analysis was performed to measure changes between pre-PSSE and Post-PSSE in these parameters.



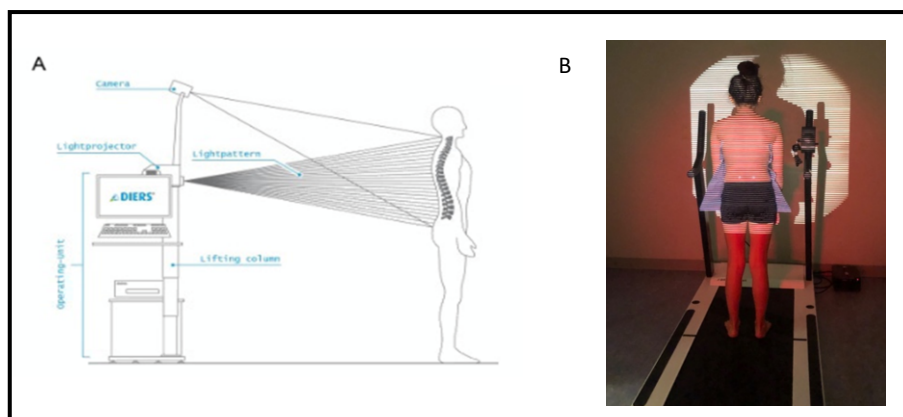


Figure 1. The DIERS Formetric 4D analysis system. (A) Illustrates the DIERS system showing the principle of triangulation. (B) Shows the anatomical landmarks (VP: vertebra prominens, DL and DR: left and right lumbar dimples. (DIERS Formetric, Diers Medical Systems, Chicago, IL).

## Results and Discussion

Six participants met the requirements, all female, and completed the treatment. After PSSE, it was demonstrated that there is an increase in COP-AP (15%) and a decrease in the COP-ML sway (-25%) (Table 1). Between pre-PSSE and post-PSSE assessments, we see that COP-OS increases on the left (16%), effectively moving away from midline, while the right foot moves closer to midline (-1%) (Table 1). The findings in this particular study may indicated the need for improved spine stability by increasing one's base of support. Furthermore, oscillation of the entire body from the midline has become more symmetrical –pre: 0.86mm and post: 0.32mm (Table 1) (Figure 2). In addition to COP, significant change was also noted in areas of max pressure of the foot post PSSE. Improvement in max pressure in the forefoot at left fifth metatarsal (-20%) and both left (35%) and right (26%) hallux, as well as changes in the right midfoot and the left rear medial foot (-22% and 15%, respectively), signifies an attempt for the patient to reach a proper equilibrium (Table 1).

The interpretations made are based on comparing outcomes in literature investigating the effects of PSSE on posture, Cobb angle and function.[2-5] The Schroth Method incorporates sensorimotor, postural and breathing exercises. It is aimed at recalibration of normal postural alignment, static/dynamic postural control and spinal stability. Spine stabilization exercises focus on improving postural balance and postural correction during static postures and functional activities.[2,3] Physiotherapeutic scoliosis specific exercises carry the characteristics of both Schroth and spine stabilization exercises. Potential limitations to this study include lack of standardization in treatment protocol, small sample size, and compliance to brace wear and/or home exercise program.

Table 1: Changes in COP and peak pressure before and after PSSE (Mean±SD, %)

Parameters	Pre-PSSE Mean±SD	Post-PSSE Mean±SD	% Change
COP (mm)			
A/P Position	0.55±0.43	0.64±0.72	15.19
M/L Position	2.10±1.60	1.65±1.18	-24.99
L Oscillation	5.87±2.90	6.97±1.25	15.82
R Oscillation	6.73±2.38	6.65±1.85	-1.26
Max Pressure (N/cm²)			
L Hallux	22.42±14.53	30.34±20.00	35.33
R Hallux	20.08±4.65	25.34±6.95	26.2
L M1	17.59±9.92	19.92±7.37	13.28
R M1	20.25±4.94	21.17±5.95	4.54
L M5	5.92±1.39	4.75±1.08	-19.72
R M5	5.25±1.13	5.17±1.72	-1.58
L Midfoot	8.00±3.74	8.58±5.12	7.29
R Midfoot	7.92±3.68	6.17±4.01	-22.1
L Rear Lateral	25.67±12.94	28.50±7.64	11.03
R Rear Lateral	21.17±5.72	21.59±9.35	1.98
L Rear Medial	27.50±13.93	31.67±9.64	15.16
R Rear Medial	32.34±6.73	23.92±11.79	2.49

(Notes: >15% changes highlighted in red)

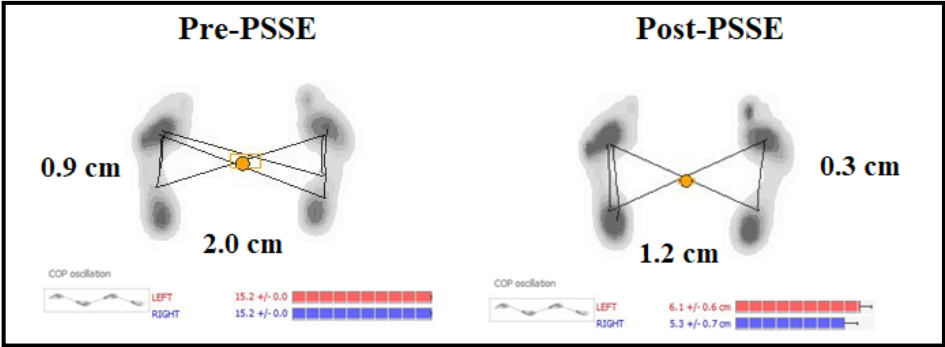


Figure 2. A 13-year -old girl with levoscoliosis had Cobb angle of 20° (T8-L1) and received 12 weeks PSSE as well as TLSO. Her COP trajectory in AP was changed from 6 cm (left) and 8.7 cm (right) to 7.1 (left) and 4.7 (right) following PSSE. Bilateral COP-OS was reduced from 15.2 cm (left and right) to 6.1 cm (left) and 5.3 cm (right). Standard deviation of COP in AP and ML were reduced from 0.9 cm, 2.0 cm, to 0.3 cm, 1.2 cm, respectively following PSSE. These findings reflected stabilization of posture and balance closed to the midline.

Conclusion and Significance

Dynamic plantar pressure analysis may suggest that PSSE intended to improve dynamic posture allows the patient’s trunk to lean forward and have less sway in the coronal plane. In addition, it appears the patient had an increase in pressure at the forefoot and medial hindfoot, suggesting improved symmetry; this occurred at heel-strike and toe-off. Pressure metrics focusing on COP-ML, COP-AP, COP-OS, and peak pressures

on the forefoot, may be considered optimal predictors to posture improvements by the means of PSSE vs utilization of static postural analysis alone.

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# Impact of corset bracing on 3D spine kinematics during ADL in children with Spondylolysis

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**Abstract:** Spondylolysis is a stress fracture of the vertebral pars interarticularis that frequently affects adolescents involved in sports. Conservative bracing methods may assist the clinician in treating spondylolysis, though there is a need to further validate these techniques. The goal of this study was to evaluate differences in the 3D movements of the thoracic and lumbar spine before and after bracing. Five patients (mean age  $14.4 \pm 1.3$  years) with spondylogenic back pain were evaluated for kinematic measurements using a Vicon motion capture system. Patients performed activities both with and without a lumbar corset brace including walking, kneeling, standing from a chair, standing from the floor, ascending and descending stairs, and lifting. Patients were evaluated for differences in thoracic and lumbar range of motion (ROM) in the braced and unbraced condition. While wearing the brace, patients demonstrated reduced extension ROM of the thoracic spine while walking (mean reduction =  $0.4^\circ$ ), ascending stairs ( $3.0^\circ$ ), descending stairs ( $2.1^\circ$ ), lifting ( $14.8^\circ$ ), standing from a chair ( $4.1^\circ$ ), standing from the floor ( $16.7^\circ$ ), and kneeling ( $8.4^\circ$ ). Patients also exhibited reduced extension ROM of the total lumbar spine while ascending stairs (mean reduction =  $1.8^\circ$ ), lifting ( $12.7^\circ$ ), standing from a chair ( $9.5^\circ$ ), standing from the floor ( $11.8^\circ$ ), and kneeling ( $4.7^\circ$ ). These results provide evidence that bracing reduces stress on the pars interarticularis and relieves symptoms in the athlete with spondylogenic back pain, thereby facilitating a return to sports.

**Keywords:** spondylolysis, adolescent athlete, kinematics, bracing

## Introduction

Spondylolysis is a stress fracture of the vertebral pars interarticularis that frequently results in low back pain in young adults, particularly those involved in sports.[1] It is thought that this defect results from repetitive flexion, hyperextension, and rotation of the trunk.[2] These motions continually put stress on the pars which wears on the bone over time, ultimately leading to a fracture. The most commonly affected area is at the level of L5, which is the vertebra that carries the greatest load.[3] It is estimated that around 90% of all spondylolysis cases occur at this level. Furthermore, the pars interarticularis is structurally the weakest part of any given vertebra, thereby making it particularly susceptible to fracture.[4] This is especially true in growing adolescents as these individuals have ossification centers in the same region of their vertebrae that experience higher stresses.[5] These stress fractures can be either unilateral or bilateral and may even occur at multiple levels within the spine.

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Spondylolysis is a relatively common condition within the pediatric population, as it is estimated that between 3 and 7% of adolescents are affected.[6] While individuals in many different sports may be affected, certain sports have demonstrated a greater link to spondylolysis than others. Studies have seen incidence rates of 15 to 20% in dancers compared with rates as high as 30% in wrestlers and 43% in divers.[7,8] The reason for these abnormally high incidence rates noted in these sports may lie in the use of excessive lordotic postures, whereby the pars interarticularis is subjected to higher stresses and is at a greater risk for fracture. Gender may also be an important determinant, as one study found a higher rate of pars defects in males than females.[9] Furthermore, males were generally affected at an earlier age than females, possibly owing to an earlier involvement in sports.

Treatment of spondylolysis generally follows a conservative approach involving a combination of activity modification, rest, and physical therapy.[10] Bracing may also be used as this approach has demonstrated some success in alleviating pain and helping to achieve bony union. This is especially true at early stages of spondylolysis as studies have demonstrated success rates over 90% in those diagnosed early on in their course.[11] It is thought that bracing helps facilitate healing in these patients by approximating fracture segments. Furthermore, bracing has been shown to decrease extension of the lumbar spine during activities such as golfing.[12] However, generally speaking, studies have been mixed and the data regarding the impact of bracing on the motion of the spine and pelvis is limited. Our experience is that brace utilization and brace types vary greatly by institution. Also, most health insurance providers do not include bracing as a covered benefit in the athlete with extension-based (spondylogenic) low back pain without a formal diagnosis of spondylolysis. As a result, the goal of this study was to evaluate differences in the three-dimensional movements of the thoracic and lumbar spinal segments before and after semi-rigid corset bracing during six activities of daily living. We hypothesized that lumbar corset bracing would lead to decreased flexion-extension range of motion at the thoracic spine in patients with presumptive spondylolysis during these activities.

## Methods

Five patients with spondylogenic back pain performed seven activities of daily living (ADL) including walking, kneeling, standing from a chair, standing from the floor, ascending and descending stairs, and lifting. These activities were performed both with and without a lumbar corset brace (R&M Rehabilitation, LLC). Kinematic measurements were taken using a motion capture system with 12 cameras sampling at 120 Hz (Vicon system, Oxford, UK). A whole-body three-dimensional model of the trunk, upper limb, and lower limb was generated from 47 reflective markers placed on the skin. Additionally, a detailed lumbar model was constructed based upon two triad wands with reflective markers at the L1 and L3 levels.[13]

Using these models, patients were evaluated for changes in thoracic and lumbar spinal motion in all three planes while performing each ADL. The calculated ranges of motion (ROM) in these spinal segments were then compared between the braced and unbraced condition. A descriptive analysis was performed that included mean and standard deviation of ROM differences before and after bracing. Due to limited sample size, no statistical tests were conducted. All methods were approved by an institutional review board prior to the onset of the study.

Results and Discussion

Five patients, 2 males and 3 females with a mean age of  $14.4 \pm 1.3$  years, were recruited for this study. These patients had a mean height of  $168.4 \pm 14.4$  cm and a mean weight of  $57.2 \pm 11.7$  kg. Two patients were involved in cheerleading, two were involved in soccer, and one was involved in dance when they began developing spondylogenic back pain. This pain was unilateral in three cases and bilateral in the other two and was located at either the L4 or L5 level. Pain was present for a mean of 2.7 months prior to presentation for this study. This pain rated from a 0 to 3 at rest and 0 to 8 with activity on the VAS pain scale. These demographic data are summarized in Table 1 below.

Table 1. Demographic information of patient participants.

Patient #	Age	Gender	Sport	VAS (rest)	VAS (activity)	Pain Duration	Stork		Double Straight Leg Lowering
							L	R	
1	13	F	Cheerleading	2	6	3 mo	+	+	3+ (fair)
2	15	M	Dance	0	4	4 mo	+	+	Deferred d/t pain
3	15	F	Cheerleading	2	2	4 mo	-	-	5 (normal)
4	16	M	Soccer	0	0	2.5 wk	-	-	4- (good minus)
5	13	F	Soccer	3	8	2 mo	-	-	4+ (good plus)

ROM measures were obtained from all patients for knee flexion (mean L =  $130^\circ$ , mean R =  $131^\circ$ ), knee extension ( $0^\circ$ ,  $0^\circ$ ), hip flexion ( $122^\circ$ ,  $124^\circ$ ), hip extension ( $29^\circ$ ,  $23^\circ$ ), hip internal rotation ( $47^\circ$ ,  $44^\circ$ ), hip external rotation ( $35^\circ$ ,  $34^\circ$ ), ankle dorsiflexion with the knee extended ( $9^\circ$ ,  $8^\circ$ ), ankle dorsiflexion with the knee flexed to  $90^\circ$  ( $18^\circ$ ,  $17^\circ$ ), and plantarflexion ( $44^\circ$ ,  $44^\circ$ ). Two patients had a positive stork test on both sides. Double straight leg lowering test ranged from 3+ (fair plus) to 5 (normal) with one patient not tested due to pain. The quadratus lumborum test was negative in all patients. Plain films of the lumbosacral spine showed a mean pelvic tilt of  $15.6 \pm 11.0^\circ$ , mean sacral slope of  $37.6 \pm 1.3^\circ$ , and mean pelvic incidence of  $53.2 \pm 1.3^\circ$ .

While wearing the brace, patients demonstrated reduced extension ROM of the thoracic spine while walking (mean reduction =  $0.4^\circ$ ), climbing stairs ( $3.0^\circ$ ), descending stairs ( $2.1^\circ$ ), lifting ( $14.8^\circ$ ), standing from a chair ( $4.1^\circ$ ), standing from the floor ( $16.7^\circ$ ), and kneeling ( $8.4^\circ$ ). Those mean reductions in thoracic extension ROM that are greater than  $4^\circ$  can be seen in Table 2 below. Patients also exhibited reduced extension ROM of the total lumbar spine while climbing stairs (mean reduction =  $1.8^\circ$ ), picking up an object ( $12.7^\circ$ ), standing from a chair ( $9.5^\circ$ ), standing from the floor ( $11.8^\circ$ ), and kneeling ( $4.7^\circ$ ). There were no changes in thoracic ROM greater than  $4^\circ$  in the transverse plane or in the lumbar ROM within the coronal plane.

Table 2. Mean reductions in thoracic and lumbar ROM after bracing (mean  $\pm$  SD, only included ROM changes  $> 4^\circ$ ).

Activity	Thoracic Extension Mean ROM Reduction	Thoracic Lateral Bending Mean ROM Reduction	Lumbar Extension Mean ROM Reduction	Lumbar Axial Rotation Mean ROM Reduction
Stand from Chair	4.1 $\pm$ 28.1 $^\circ$		9.5 $\pm$ 12.6 $^\circ$	
Stand from Floor	16.7 $\pm$ 5.9 $^\circ$		11.8 $\pm$ 0.9 $^\circ$	24.0 $\pm$ 39.4 $^\circ$
Kneeling	8.4 $\pm$ 8.8 $^\circ$		4.7 $\pm$ 6.6 $^\circ$	
Lifting	14.8 $\pm$ 5.2 $^\circ$	-6.8 $\pm$ 14.3 $^\circ$	12.7 $\pm$ 12.2 $^\circ$	
Walking				
Ascending Stairs		4.1 $\pm$ 2.9 $^\circ$		
Descending Stairs		5.4 $\pm$ 3.6 $^\circ$		

Bracing resulted in reduced flexion-extension ROM of the thoracic and lumbar spine. While this was demonstrated during all activities, it was especially apparent while standing from a chair, standing from the floor, kneeling, and lifting. This is likely because these activities generally involved greater motion of the spine in the sagittal plane, unlike activities such as walking or navigating stairs where flexion-extension motion of the spine is minimal. In general, it appeared that walking did not result in noticeable changes in spinal motion with the lumbar corset brace, regardless of the plane or spinal segment considered.

Bracing did not appear to have any considerable impact on spinal motion in the transverse or coronal plane across all activities, as there were few changes seen in thoracic ROM with lateral bending or lumbar ROM with axial rotation. Although there was a considerable reduction in lumbar rotational ROM when standing from the floor for some patients, this result was not consistent across all patients. Interestingly, bracing actually resulted in increased thoracic lateral bending ROM while lifting for some patients. However, this result was only seen in a minority of patients and may have occurred secondary to improper positioning of the patient behind the object being lifted.

While the results of this study are not particularly surprising, they do suggest that the primary benefit of bracing is reduced motion of the spine during everyday activities. This likely leads to decreased stress on the pars interarticularis and helps to minimize pain during activities. This may explain why most young athletes with spondylolysis who are treated conservatively are able to return to sports in the months following their injury.[14,15] Furthermore, bracing may also result in reduced motion at the pars itself, thereby facilitating bony union in these patients. This is consistent with what other studies have found as bracing has been shown to result in high rates of bony union when treated early on in its course.[11]

One of the primary limitations of this study is a small sample size. This undoubtedly will limit the ability to generalize the results of this study to the larger population and makes it difficult to draw conclusions about the effect of bracing on spinal kinematics. However, this small sample size is to be expected given the nature of this study as a pilot study. This will be remedied with future studies as more data are collected on additional subjects. Another limitation of this study is poor visualization of the lumbar spine due to

occasional interference from the lumbar corset brace. These instances seemed to be relatively uncommon, however, and trials were repeated whenever this was observed during the course of data collection. In general, it does not appear that these signal dropouts had any significant impact of the data that were obtained.

## Conclusion and Significance

Lumbar corset bracing tends to result in reduced range of motion in the thoracic and lumbar spine in the sagittal plane during mild to moderate activities of daily living. This was especially apparent during activities such as standing from a seated position, kneeling, and lifting. These results provide evidence that bracing reduces stress on the pars interarticularis and relieves symptoms in the athlete with spondylogenic back pain, thereby facilitating a return to sports.

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# Evaluation of plantar pressures and center of pressure trajectories in Adolescent Idiopathic Scoliosis

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**Abstract:** Adolescent idiopathic scoliosis (AIS) has been postulated to affect gait patterns and postural stability due to its effect on center of body mass. 1) Determine the correlation between Cobb angle and COP in the anterior-posterior (AP) direction, COP in the medial-lateral (ML) direction, COP oscillation (COP-O) from midline walking, peak pressures, and pressure-time integrals (loading) at 10 anatomic foot segments; 2) Determine the differences in COP-AP, COP-ML, COP-O, and peak plantar pressures at 10 anatomic foot segments between the normal group and the AIS group. All patients wore a gown to expose the posterior trunk and underwent evaluation with Formetric 4D (DIERS International GmbH, Schlagenbad, Germany) while walking on the treadmill at 2 km/hour for 15 seconds. A total of 24 pressure metrics at 10 anatomic foot segments were evaluated. We then analyzed the data using t-test and linear regression analyses. 16 patients were assigned to a normal group (Cobb angle 10° or less, n=4) or AIS group (Cobb greater than 10°, n=12). Of note, AIS patients had statistically significant lower max. pressures at the hallux and the 2<sup>nd</sup>, 4<sup>th</sup>, 5<sup>th</sup> metatarsal head compared to the normal group. Additionally, there was a statistically significant linear association between Cobb angle and both hallux max. pressure and hallux pressure-time integral (P<0.05). Reduced peak plantar pressures before the toe-off phase of gait cycle indicate that AIS patients may lean backwards and have posterior postural sway, which may be associated with hypokyphosis during walking.

**Keywords:** Peak pressure, COP, AIS, Posture

## Introduction

Adolescent idiopathic scoliosis (AIS) arises in 1-4% of adolescents during the early stages of development and is more common in female patients than male patients.[1] The etiology of AIS remains unknown and has largely been ascribed to being multifactorial. However, some studies have considered the possibility of the development of scoliosis through impaired axial muscle control.[2] Some of these changes have been postulated to be due to a disharmony between autonomic and somatic nervous systems leading to scoliosis.[3] A review by Daryabor et al. showed that AIS patients had decreased hip and pelvic motion, excessive energy cost of walking, stepping pattern asymmetry, and ground reaction force asymmetry.[4] Our previous study demonstrated that AIS patients treated with posterior spinal fusion had increased gait velocity, cadence, and torso displacement in the sagittal plane but reduced truncal rotation as compared to normal patients.[5] Additionally, there were significant reductions in pelvic tilt, hip ROM, and

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knee ROM. Furthermore, there is a reduction in the area, mean, and peak values of each EMG phase (flexion and extension) in trapezius, latissimus dorsi, and multifidus activity during forward flexion, extension, and lateral bending in patients who were treated with posterior spinal fusion. This study suggests that kinematic and kinetic changes in AIS patients after posterior spinal fusion could affect static or dynamic stability.[5]

Past studies have demonstrated that COP (Center of Pressure) shift is a reliable marker of standing stability and neuromuscular control of posture sway.[4] Center of Pressure trajectories show a butterfly-like pattern, reflecting shifts in weight in the medio-lateral and anterior-posterior direction.[6] Furthermore, Dufvenberg et al. has performed a systematic review to show that AIS patients have decreased postural stability as measured by increased COP. AIS patients were shown to have a posterior shift in position in the sagittal plane.[7]

There have also been multiple reports of the correlation of scoliotic curves and static plantar pressures. Hoppenfeld et al. demonstrated a statistically significant change in the sagittal plane of AIS patients treated with bracing based on the severity of the curve.[8] Patients with curves less than 40 degrees treated with bracing did not demonstrate altered plantar weight-bearing distribution. However, patients with curves greater than 40 degrees treated with bracing had their plantar weight shift towards the forefoot. Meanwhile, surgically treated patients had increased pressures on their hindfoot, likely due to the magnitude of their curve. The authors conclude that these findings suggest that a normal mobile lumbar spine is critical for maintaining normal center of gravity. When the deviation of the spine exceeds the critical point associated with curve progression, there are consequential alterations in plantar pressures.[8]

AIS patients who are subjected to abnormal loading patterns daily during daily walking may develop back pain or other musculoskeletal consequences later in life. Gao et al. also argues that changes in COP trajectories could suggest either impaired neurological control for gait or biomechanical misalignment between the spine and plantar surface which affects loading impact on the foot.[9] These changes could result in asymmetric back pain or changes in neuromuscular control of muscles at the ankle joint.

Previous studies allowed subjects to walk at their own selected pace which may affect the magnitude of their peak plantar pressures. Additionally, these studies failed to identify plantar pressures at different anatomic foot regions. The objective of this study was to determine: 1) correlation between Cobb angle and COP in the AP direction, COP in the ML direction, COP-O from mid line, peak pressures, and pressure-time integrals (loading) at 10 anatomic foot segments while subjects were walking on the treadmill with a constant speed; 2) differences in COP-AP, COP-ML, COP-O, and peak plantar pressures at 10 anatomic foot segments between the normal group and the AIS group.

## **Methods:**

A retrospective review of an institutional database was performed. All patients wore a gown to expose the posterior trunk and had markers placed on T1, left posterior superior iliac spine, and right posterior superior iliac spine. Patients then underwent evaluation with Formetric 4D (DIERS International GmbH, Schlangenbad, Germany) while walking on the treadmill at 2 km/hour for 15 seconds. Each patient had one trial during the study. A total of 24 pressure metrics at 10 anatomic foot segments were evaluated, including butterfly-like shifts in Center of Pressure in AP or ML direction,

bilateral difference of COP-O from midline, peak pressures, and pressure-time integral. We then analyzed the data using t-test and linear regression statistical analyses. We considered p-values <0.05 to be statistically significant.

## Results and Discussion:

Sixteen patients were assigned to a normal group [mean Cobb angle=8° (5-10°), age=12.64, all female, n=4] or AIS group [mean Cobb =21° (11-57°), age=12.59, 2 male, 10 female, 5 right-sided major curves, 7 left-sided major curves, n=12] (see Table 1) .

Table 1: Demographic Comparisons between Normal and AIS patients (Mean and min. to max.)

	Normal ( $\leq 10^\circ$ )	AIS ( $> 10^\circ$ )
Sample Size	4	12
Male	0	2
Female	4	10
Age (years)	12.6	12.6
Mean Cobb Angle	8° (5-10°)	21° (11-57°)

Our studies showed that AIS patients had statistically significant lower max. pressures at the hallux and 2<sup>nd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> metatarsal head compared to the normal group (see Table 2). While we did notice reductions in lower max. pressures in the 1<sup>st</sup> and 3<sup>rd</sup> metatarsals, they were not statistically significant (p-value>0.05). There were no statistically significant differences in COP ML, COP AP, or bilateral COP-O from midline between two groups (see Table 2). AIS patients had statistically significant greater hallux max. pressures and hallux pressure-time integral when compared to normal patients (Table 2).

Table 2: Comparisons of peak pressures and COP displacement between normal and AIS (Mean  $\pm$  SD)

	Normal ( $\leq 10^\circ$ )	AIS ( $> 10^\circ$ )	p-value
M1 Max Pressure (N/cm <sup>2</sup> )	13.3 $\pm$ 2.03	12.69 $\pm$ 2.40	0.7
M2 Max Pressure (N/cm <sup>2</sup> )	22.7 $\pm$ 4.99	15.2 $\pm$ 5.07	0.02
M3 Max Pressure (N/cm <sup>2</sup> )	19.6 $\pm$ 4.51	13.9 $\pm$ 5.45	0.08
M4 Max Pressure (N/cm <sup>2</sup> )	16.7 $\pm$ 5.4	9.61 $\pm$ 3.48	<0.01
M5 Max Pressure (N/cm <sup>2</sup> )	9.81 $\pm$ 4.92	5.71 $\pm$ 2.21	0.03
COP AP	0.55 $\pm$ 0.27	0.78 $\pm$ 0.47	0.36
COP ML	1.82 $\pm$ 1.52	2.08 $\pm$ 1.34	0.75
Bilateral COP Oscillation from Midline	4.88 $\pm$ 1.63	5.43 $\pm$ 2.31	0.67
Hallux Max Pressure (N/cm <sup>2</sup> )	17.1 $\pm$ 5.14	19.5 $\pm$ 9.59	<0.01
Hallux pressure-time Integral (N/cm <sup>2</sup> ·s)	3.59 $\pm$ 1.21	3.69 $\pm$ 1.46	0.01

Gao et al. evaluated COP progression of normal and AIS patients during gait in the forefoot, midfoot, and hindfoot regions in both feet. The authors found that there was increased medial-lateral displacement in the normal groups compared to the mild idiopathic scoliosis group (average cobb angle=19.9) in the midfoot of the ipsilateral foot, relative to the major curve. On the contralateral foot, relative to the major curve, the patients had increased anterior-posterior displacement in the hindfoot of the normal group compared to the mild AIS group.[9] In contrast, our study showed that AIS patients had an increased tendency for COP deviation in the ML plane when compared to normal subjects, despite no statistically significant differences. In our study, COP butterfly deviation was measured from the center of bilateral limbs during the single leg stance rather than evaluating COP in the hind foot, midfoot and forefoot regions. Additionally,

our study showed COP-O from midline during gait, indicative of the base of the support, which was increased in the AIS group ( $P>0.05$ ).

There were no statistically significant correlations between COP ML, COP AP, or bilateral COP-O from midline and Cobb angle. However, there was a statistically significant correlation between the Cobb angle and both hallux max. pressure and hallux pressure-time integral in both the left and right feet. The correlation of hallux max pressure to Cobb angle is 0.856 on the left foot and 0.654 on the right foot ( $p\text{-value}<0.01$ ). The correlation of hallux pressure-time integral to Cobb angle is 0.542 on the left foot and 0.464 on the right foot ( $p\text{-value}<0.01$ ) (see Figure 1). This may be due to the fact that 7 of the AIS patients had left sided major curves while 5 of the AIS patients had right sided major curves. Our finding is similar to a prior study that has shown that AIS children with a major moderate lumbar levoscoliosis tended to have significantly increased loads on the left foot (54% body weight distribution) compared to the right (46%), whereas there is an inverse relationship between the lumbar Cobb angle and right 5<sup>th</sup> metatarsal head.[10]

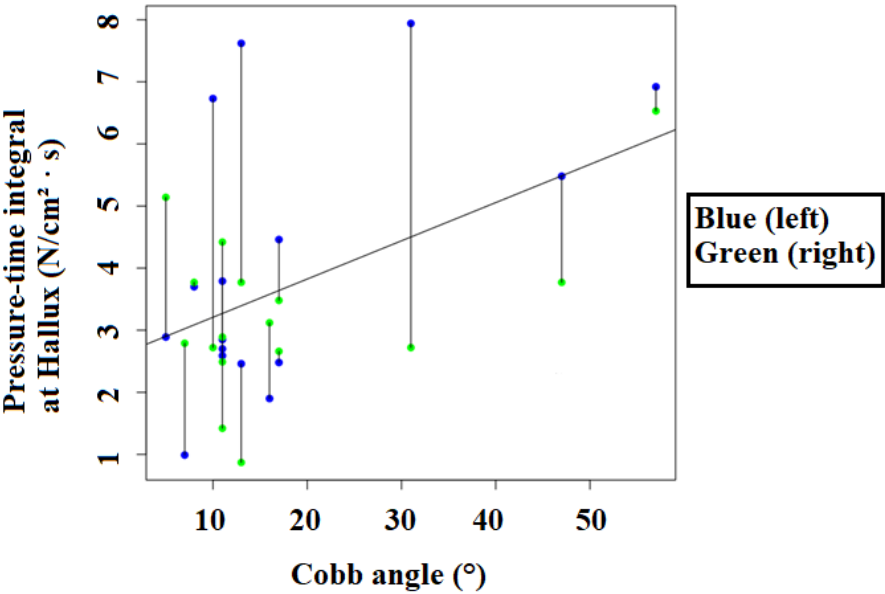


Figure 1. Linear relationship between pressure-time integral at the left or right hallux and Cobb angle ( $r$  at left hallux=0.54,  $r$  at right hallux=0.46,  $P<0.01$ )

Conclusions and Significance

Given the evidence of significant differences in the peak pressure at the hallux and the 2<sup>nd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> metatarsal head between normal and AIS patients, dynamic pressure analysis could be a better predictor in the evaluation of postural stability for children with AIS. Statistically significant reduced peak plantar pressures at the beginning of the toe-off phase of gait cycle indicate that AIS patients may lean backwards and have

posterior postural sway, which may be associated with hypokyphosis during walking. These patients may benefit from more physiotherapeutic interventions.

Some limitations of this study are the small sample sizes as well as no long-term follow up. A prospective study is needed to better understand differences in pressure parameters between the two groups as well as the within-group comparisons.

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# An inertial sensor-based protocol for spinal range of motion measurements

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**Abstract:** To develop a protocol for assessing spinal range of motion using an inertial sensor device. The baseline error of an inertial sensor was assessed using a bicycle wheel. Nineteen healthy subjects (12 females and 7 males, average age 18.2 ± 0.6 years) were then prospectively enrolled in a study to assess the reliability of an inertial sensor-based method for assessing spinal motion. Three raters each took three measurements of subjects' flexion/extension, right and left bending, and right and left rotation. Afterwards, one trial from each set of measurements was excluded. Correlations and the ICC (3,1) were used to assess intra-rater reliability, and ICC (3,2) was used to assess inter-rater reliability of the protocol. The baseline error of the sensor was 1.45°. Correlation and ICC (3,1) values for the protocol all exceeded 0.888, indicating high intra-rater reliability. ICC (3,2) values for the protocol exceed 0.87, indicating high inter-rater reliability. Our study presents both a paradigm for assessing the baseline error of inertial sensors and a protocol for assessing motion of the spine using an inertial sensing device.

**Keywords:** Inertia sensor, spine motion, reliability

## Introduction

Range of motion measurements are one of the cornerstones of clinical practice in musculoskeletal care. In conventional motion assessment of the extremities, the six distinct motions of the spine are measured using a tape measure, goniometer, or dual inclinometer.[1-4] These measurement techniques are difficult to use when assessing the range of motion of the spine. Unlike joints like the knee or elbow, the spine can move freely within all six degrees of freedom, and isolation of the spine's motion in separate planes is difficult. Moreover, measurements using tape measures or dual inclinometers rely heavily on the test administrator's ability to reliably locate anatomical structures such as vertebra C7 and the posterior superior iliac spine (PSIS) at the skin surface multiple times during one assessment.[5] Currently, there is no strong recommendation for a tool or modality to measure spinal motion.[6] Recently, inertial sensor-based methods for assessing motion have been proposed as replacements for conventional methods. Inertial sensors are electronic devices that can measure and report on parameters like orientation, position, and velocity.[7] Despite previous attempts to validate inertial sensor-based protocols for measuring spinal motion, we need insights

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into (1) sensor hardware used for motion assessment as well as (2) potential confounds during clinical motion tests before inertial sensor-based practices are standard for assessing spinal motion.

The purpose of this study was to develop a protocol for assessing spinal motion based on an inertial sensor. We first develop a novel experimental paradigm using a bicycle wheel to examine the baseline error of our inertial sensor. We then present our protocol for assessing spinal motion in healthy subjects. Our work examining baseline sensor error provides insight into the potential confounds with the clinical range of motion measurements. Following a data cleaning procedure, we demonstrate that our protocol has excellent intra- and inter-rater reliability. Finally, our work provides recommendations for future development of spinal range of motion protocols.

## Methods

### *Baseline Sensor Error Assessment*

A bicycle wheel was positioned with the edge of the tire facing a Bluetooth receiver and the hub of the bicycle facing the walls adjacent to the receiver. An inertial sensor (DIERS International GmbH, Schlangenbad, Germany) was secured to the edge of the tire. This arrangement simulated sagittal motion. The sensor was calibrated by rotating the bicycle downwards  $10^\circ$ . Three different testers moved the bicycle wheel to a maximum angular displacement of  $\pm 30^\circ/\pm 65^\circ/\pm 100^\circ$  over three trials per angle per tester. The bicycle wheel was then positioned with the hub facing the Bluetooth receiver. This configuration mimics motion assessment in the coronal plane. After calibrating the sensor, three different testers moved the bicycle wheel to a maximum angular displacement of  $\pm 30^\circ/\pm 50^\circ/\pm 70^\circ$  over three trials per angle per tester. Finally, the bicycle wheel was then positioned with the hub facing the ceiling and floor. This configuration mimics motion assessment in the axial plane. After calibrating the sensor, three different testers moved the bicycle wheel to a maximum angular displacement of  $\pm 30^\circ/\pm 50^\circ/\pm 70^\circ$  over three trials per angle per tester. The plane-specific errors of the sensor were then estimated.

### *Subject Enrollment.*

Following Institutional Review Board (IRB) review and approval from St. Peter's Hospital in New Brunswick, NJ, 19 subjects were enrolled in a prospective study conducted at the Institute for Spine and Scoliosis in Lawrenceville, NJ from September 2019 to November 2019. Our cohort consisted of 12 females and 7 males of average age  $18.2 \pm 0.6$  years at the time of enrollment. Permission to participate in the study was obtained from guardians of all subjects aged younger than 18.

### *Measurement of Spinal Range of Motion.*

For each subject enrolled in this study, the same inertial sensor was affixed to the surface of the skin above vertebra C7 with a piece of skin-sensitive tape. To prevent any interference with Bluetooth sensing, subjects with long hair tied up their hair, and subjects removed articles of clothing that obscured the skin over vertebra C7.

Throughout the range of motion measurements, the subject faced a Bluetooth receiver. At the beginning of each measurement session, the subject bent slight towards the Bluetooth receiver to calibrate the sensor. Subjects were then asked to bend forwards and backwards to assess sagittal motion. Subsequently, subjects were prompted to bend to the left and right to assess coronal motion. Finally, subjects were seated and instructed to rotate to the left and right to assess axial motion. During the measurements, subjects were instructed to minimize motion of the neck and hips. Moreover, subjects were instructed to minimize motion of the spine in planes other than the one of interest for measurement. While standing, subjects placed their hands on their hips, and the test administrator provided resistance to the subjects' knees while seated. The same range of motion procedure was administered independently by three trained administrators employed at our clinic, and each subject performed the range of motion procedure three times per administrator on the day of study enrollment. *Data Cleaning and Statistical Analysis.* For each subject and rater, we rejected one trial of every motion. The trial that was removed had the greatest magnitude difference from the median of the three-trial set. In the case that the non-median measurements were equidistant from the median, the maximum value of the trial set was eliminated. Data sets were first analyzed using the Shapiro-Wilk Test for normality. Pearson's/Spearman's  $r$  values and ICC (3,1) values were calculated to assess intra-rater reliability of the sensor using validated MATLAB code (MATLAB R2018a, Mathworks, Natick, MA). ICC (3,2) values were calculated for each measure using MATLAB to assess the inter-rater reliability of the sensor. Errors for each measurement were then estimated by averaging the standard deviations over all sets of trials.

## Results and Discussion

To estimate the baseline error of the sensor, we performed an extensive baseline error assessment of the inertial sensor using a bicycle wheel. This paradigm allowed us to isolate individual motion planes and to simulate the motion tasks a subject performs in a clinical setting. These results are summarized in Table 1. To estimate the error of the device, we averaged the errors from each of the simulated planes, obtaining a sensor error of  $1.45^\circ$ . To assess the protocol's reliability, we used motion measurements from 19 subjects taken in triplicate by three trained test administrators. ICC (3,1) values are summarized in Table 2. ICC (3,1) values are all above 0.934. For all ICC (3,1) values,  $p < 1e-10$ ,  $df_1 = 18$ ,  $df_2 = 18$ . Together, the ICC (3,1) values for the three raters in this study indicate the inertial sensor exhibits high intra-rater reliability. The inter-rater reliability of the inertial sensor was determined using values of ICC (3,2), highlighted in Table 3. We selected the ICC (3,2) value as a metric for inter-rater reliability because we compared the averages of two separate trials measured by trained test administrators. All spinal motions exhibit ICC (3,2) values above 0.87. For all ICC (3,2) values,  $p < 1e-7$ ,  $df_1 = 17$ ,  $df_2 = 34$ . Our protocol for measuring spinal range of motion exhibits excellent inter-rater reliability among trained administrators.



Table 1. Summary of baseline inertial sensor errors. The errors for each plane are calculated as the average of the standard deviations over all testers and displacements (n = 9), and the device error is the average of the errors of the three planes (n = 3).

	Error (°)
Simulated Sagittal Plane	1.56
Simulated Coronal Plane	1.68
Simulated Axial Plane	1.11
Overall Device	1.45

Table 2. Summary of ICC (3,1) values for the six different range of motion measurements of interest for three individual raters (n = 19 for all). For all ICC (3,1) values,  $p < 1e-10$ ,  $df1 = 18$ ,  $df2 = 18$ .

Measure	Rater 1	Rater 2	Rater 3
Flexion	0.988	0.957	0.989
Extension	0.980	0.985	0.983
Right Bending	0.966	0.951	0.982
Left Bending	0.963	0.986	0.993
Right Rotation	0.951	0.956	0.969
Left Rotation	0.983	0.934	0.975

Table 3. Summary of ICC (3,2) values for the six different range of motion measurements. For all ICC (3,2) values,  $p < 1e-7$ ,  $df1 = 17$ ,  $df2 = 34$ .

Measure	ICC (3,2)
Flexion	0.944
Extension	0.912
Right Bending	0.934
Left Bending	0.944
Right Rotation	0.952
Left Rotation	0.879

*Rationale for Baseline Error Assessment*

Our study provides both insights into and a paradigm to assess the baseline error of an inertial sensor. By providing errors for different planes of motion, we provide a way for clinicians who use inertial sensors to deconvolute the error of a protocol into baseline error associated with the sensor and the error associated with patient-induced variability. Because we have provided the error of the examiner and hardware as 1.45°, in our protocol, we can attribute variability larger than this to the subject.

*Rationale for Data Cleaning Procedure*

Before analyzing our data with descriptive statistics, we rationalized that the differences among trials were either due to (1) the error associated with measuring a subject’s motion or (2) the subject realizing at least two distinct motion potentials over the three trials of measurement. The purpose of range of motion assessment is to estimate the maximum motion potential a subject can repeatedly exhibit for a given motion. Accordingly, we examined the ranges of the motion potentials measured over three trials to ensure that factor (2) did not confound our data. When we examined the ranges of the three trials for all sets of measurements, we found that 46/342 (~13%) sets of measurements exhibited ranges larger than 15°. Based on our baseline sensor error assessment, we found the error of the sensor to be 1.45°. Accordingly, assuming the measurement error is distributed normally around the subject’s true motion potential, a range of 15° represents ten standard deviations around the subject’s motion potential. If a subject repeatedly achieves the same motion potential over any number of

measurement trials, 99.99% of the trials should fall within the  $15^\circ$  range corresponding to the (motion potential)  $\pm 5^\circ$  (sensor error). In light of these observations, we hypothesized that factor (2) was a confound in our data set. To reduce the effect of factor (2), we eliminated the trial with the greatest magnitude difference from the median of the three-trial set from all sets of three trials.

### *Reliability of our Protocol*

Together our results suggest that our protocol is a highly reliable way to assess spinal range of motion in healthy subjects. The values for ICC (3,1) indicate that between trials, individual raters measure highly consistent values for a subject's motion potential. Likewise, for inter-rater reliability, our values for ICC (3,2) all fall between 0.87 and 0.96, indicating excellent reliability among trained test administrators. Previous attempts to assess range of motion, using both traditional methods and inertial sensors, suffered from high errors and poor/fair reliabilities. We rationalize that poor error and reliability may be due to at least two major factors: (1) the error of the tool used for the protocol (particularly relevant for traditional methods) or (2) the subject exhibiting distinct motion potentials in different measurement trials. Our work in this study suggests that for three repeated trials of assessing motion in the spine, subjects may exhibit at least two distinct motion potentials.

## **Conclusions and Significance**

In this study, we developed a protocol for assessing spinal range of motion using an inertial sensor device. Compared to other protocols, ours is highly reliable and associated with low values of error. Our protocol exhibited high intra-rater reliability, with ICC (3,1) values for the protocol all exceeding 0.888. Moreover, the inter-rater reliability was also excellent, with ICC (3,2) values for the protocol exceeding 0.87. Ultimately, our study presents both a paradigm for assessing the baseline error of inertial sensors and a reliable protocol for assessing spinal range of motion in a clinical setting.

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# Artificial intelligence data-driven 3D model for AIS

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**Abstract:** Scoliosis is a 3D deformation of the spinal column, characterized by a lateral deviation of the spine, accompanied by axial rotation of the vertebrae. Adolescent Idiopathic Scoliosis (AIS), is the most common type, affecting children between ages 8 to 18 when bone growth is at its maximum rate. The selection of the most appropriate treatment options is based on the surgeon's experience. So, developing a clinically validated patient-specific model of the spine would aid surgeons in understanding AIS in early stages and propose an efficient method of treatment for the individual patient. This project steps include: Developing a clinically validated patient-specific Reduced Order Finite Element Model (ROFEM) of the spine, predicting AIS progression using data mining and proposing a method of treatment. First we implement FE synergistically with bio-mechanical information, image processing and data science techniques to improve predictive ability. Initial geometry of the spine will be extracted from the x-ray images from different planes and imported to FEM software to generate the spine model and perform analysis. A RO model is developed based on the detailed spinal FEM. Next, a neural network is used to predict the spinal curvature. The ability to predict the severity of AIS will have an immense impact on the treatment of AIS-affected children. Access to a predictive and patient-specific model will enable the physicians to have a better understanding of spinal curvature progression. Consequently, the physicians will be able to educate families, choose the most appropriate treatment option and assess for surgical intervention.

**Keywords:** Adolescent Idiopathic Scoliosis, Finite Element Model, 3D Modeling, Spine

## Introduction

Scoliosis, 3D deformation of the human spinal column, is characterized by a lateral deviation of the spine, accompanied by axial rotation of the vertebrae. In this proposal, the primary focus is on Adolescent Idiopathic Scoliosis (AIS), the most common type of scoliosis, affecting children between ages 8 to 18 when bone growth is at its maximum rate. The treatment of scoliosis is highly dependent on the scoliosis curve shape. Currently, the selection of the most appropriate treatment options are based on the surgeon's experience. So, developing a clinically validated patient-specific model of the spine would aid surgeons in understanding AIS in early stage and propose an efficient method of treatment for individual patient. This project has three steps: 1) Developing a clinically validated patient-specific Finite Element Model (FEM) of the spine, 2) Predicting AIS progression using data mining, and 3) Proposing an efficient method of treatment.

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1) *Developing a clinically validated patient-specific Finite Element Model (FEM) of the spine:* In the first step of the project, a clinically validated patient-specific FEM of the human spine including vertebra, vertebral growth plate, and intervertebral discs will be generated. Later, initiation and induction of scoliosis will be studied with the FEM of the human spine focusing on the middle column of the spine.

2) *Predicting AIS progression using data mining:* The next step of the project will be predicting a patient-specific curvature progression of an AIS spine over a period based on initial variables such as spine geometry, patient weight, and daily activity. A system of Neural Networks will be designed and trained based on the wide range of results obtained with FEM in Step 1 of the project. By integrating knowledge from mechanics, it will be made sure that the designed Neural Network has the capability to accurately predict the curvature of spine outside its training dataset.

3) *Proposing an efficient method of treatment:* Based on the results obtained in section 2, progression of scoliosis will be classified. For each group, an effective therapy program will be proposed to target the affected area and modify curvatures in an optimized way. Based on the rib cage angle and severity of scoliosis the treatment could include observation, physical therapy, and patient-specific braces for mild to moderate deformities or surgical intervention for severe deformities.

## Methods

### *Objective and Outcomes*

The anticipated outcome of the proposed work is a general, predictive, computational, and patient-specific model for the human spine considering detailed parts including the vertebral body, intervertebral discs and bone growth plates. The effort builds on data-driven principles within mechanics with the potential for investigating other spinal deformities such as kyphosis and lordosis. This will enable the clinicians to design a treatment method focusing on the critical parts of the spine which control the curvature. This is where our ongoing experimental and computational efforts can provide a prediction of the outcome of the curve and a plan of the appropriate long-term treatment method from the initial patient evaluation method. The treatment of scoliosis is highly dependent on the scoliosis curvature. Currently, the selection of the most appropriate treatment options is based on the surgeon's experience. Therefore, developing a clinically validated patient-specific model of the spine would aid surgeons in understanding AIS at an early stage and propose an efficient method of treatment for individual patients. This research proposes an improved finite-element neural network (FENN), embedding a FEM in a neural network structure, for solving the problem and predicting the spine curvature.

The goal is to construct and demonstrate a new theoretical and computational model for predicting human spine curvature over years. This effort will leverage our expertise in the biomedical engineering field to understand the cause of AIS and the role of bone growth in forming the spinal curvature. In addition to developing and advancing theoretical understanding, this will support development and designing spinal correction tools such as braces and correcting rods by monitoring how they affect spinal curvatures over a certain time period. Here we define a data-driven method as a simulation technique that depends upon manipulation of large amounts of information to deduce trends, system statistics, or parameters that would otherwise be elusive. The focus of the

proposed work is on the mechanics of bone growth and its effect on spinal curvature, leveraging existing data mining technologies. Key outcomes include:

1. Developing a clinically validated patient specific predictive model of the human spine
2. Proposing an efficient patient specific method of treatment

### *FEM model*

Finite element method (FEM) is a powerful tool that helps to understand the functional biomechanics of the spine. Current FEM models of the spine generally account for a single distinct geometry and one set of material properties and are validated with limited experimental cases. This fact raises questions concerning the predictive ability, the range of results and agreement with *in vitro* and *in vivo* values of these models.

Our proposed research methodology uses FEM synergistically with bio-mechanical information, image processing, and data science techniques to improve their predictive ability. Initial geometry of the spine will be extracted from the x-ray images which are taken from different planes. Later, these images will be imported to the FEM software to generate the spine model and perform FE analysis. The x-ray images will be provided by Lurie Children's Hospital. Since the longitudinal growth of long bones and vertebrae occurs in cartilaginous growth plates,[1] in this study the progressive growth will be applied to these plates using a conceptual model corresponding to the biological process of long bone growth. The material properties of different parts will be updated dynamically which is a significant novelty of the proposed methodology. Moreover, research has shown that AIS is associated with low bone mass and supplementing calcium and vitamin D improves bone strength and helps reduce curve progression in AIS.[2] The developed FE model can incorporate the effect of bone mineral density (BMD) on the curve progression as well.

### *Neural network design from database generated by predictive model*

In this task, a neural network will be trained to make real-time predictions of spine curvatures of AIS patients. In order to design the network, a database will be generated by running the predictive model with different samples. This database will contain the clinical data and physical information of the patients. Neural network will analyze the database and train itself to predict the spinal curvature in real-time based on current shape of the spine. This procedure will reduce the calculation time compared with predictive data-driven model. Neural network will predict stress distributions by reading the patient's specific spine geometry. After this procedure, the growth strain will be predicted based on the theory above. The spine's curvature can be predicted by repeating these processes. This framework can provide real-time growth prediction for a specific patient's spine, which will be helpful in the treatment design.

### *Treatment design*

For moderate spinal deformities, bracing is the most common treatment whereas for more severe deformities, spinal fusion surgery is warranted. The biomechanical influence on the spine is not fully understood and the efficiency in preventing the progression of scoliosis deformities is still controversial. In general, brace design and the

correcting rod are related to external force correction. The goal for this phase is to give real-time design suggestions based on the applied external force for a specific patient. In this part, an automatic self-learning algorithm will be trained to give treatment path suggestions. The function of a brace and correcting rods is to apply the force to a patient's spine to correct scoliosis. A good treatment path will suggest different brace designs or correcting rods at different stages of the treatment period. The proposed self-learning algorithm will give real-time design suggestions according to the history data and current curvature. The methodology we use is modified reinforcement learning. Reinforcement learning is an area of machine learning to maximize the cumulative reward by taking a series of actions.[3,4] It is efficient when the system is a highly nonlinear implicit black box. However, this requires a quick calculation for each step with each action. The real-time prediction can be reached by using the generated neural network.

After the training, as shown in Fig. 1, reinforcement learning proposes a treatment method based on the initial spine geometry. After applying the treatment force, the next spine state will be calculated using a neural network. If the predicted shape of the spine is not desirable the external forces will be updated accordingly. Reinforcement learning will enact a series of actions that make sure the states meet the requirements. After getting the treatment forces, an inverse design will propose a series of brace shape or correcting rods for each specific treatment time period.

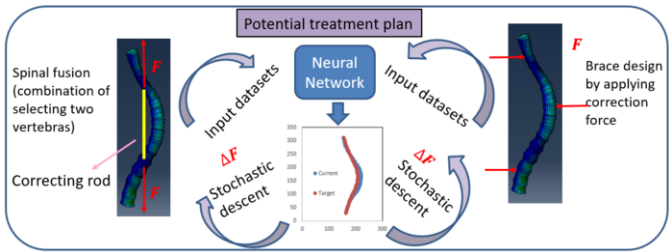


Figure 1: An overall step of proposing treatment path based on initial geometry

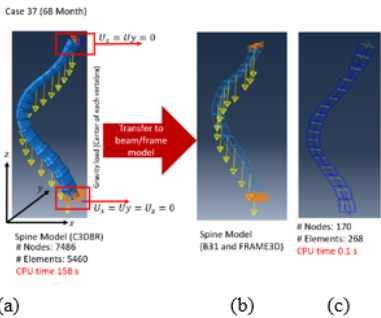


Figure 2: (a) load and boundary conditions applies on the model with continuum elements (b) boundary conditions applied on the simplified model (c) simplified model of spine

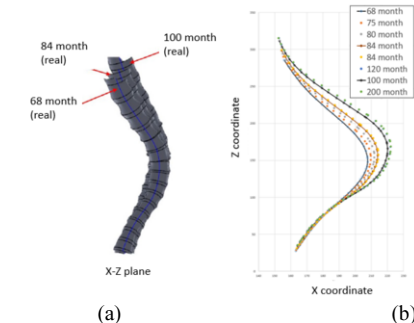


Figure 3. (a) 3D geometry of predicted spine (b) center points for all the predicted shapes and real shapes.

## Results and Discussion

In the first step of the project, a reduced order model is developed based on the detailed FE model of the spine. Fig 2 shows a preliminary result of the reduced order model which the CPU time decreases from 158 s to 0.1 s.

In the second step of the project, a neural network is used to predict the spine curvature. Figure 3a shows the 3D model of a predicted spine curvature and the ground truth spine curvature. Figure 3b shows the middle line of all the predicted spine and ground truth spines. As shown in 3b, the algorithm can predict every single month's spine curvature and matches.

## Conclusion and Significance

The physicians require real-time prediction of curvature in spine of AIS patients to prescribe most suitable path of treatment. If braces are to be designed for treatments, the design must consider the change in the shape of AIS patient's spine over the period of treatment. Therefore, the brace designers also require a real-time predictive scheme for proper design. Our proposed methodology offers a real-time predictive scheme while considering all the complex factors including geometry, material property, physical conditions, etc. For fast calculation we will develop a physics-based reduced order model and incorporate that into our computational scheme. Moreover, the geometrical update will also be performed based on unsupervised learning assisted clusters on vertebral growth plates. Thus, the model will be able to calculate and predict the shape of vertebrae very quickly and the physicians can visualize the progression of spine in real time. This is another unique feature of the proposed model making it suitable for implementation in hospitals. The entire methodology is very general from computational point of view and can be adopted to treat other spinal diseases like Lordosis and Kyphosis. Therefore, the scheme has broader impact on the treatment of spinal deformities.

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# Advancements in data analysis and visualisation techniques to support multiple single-subject analyses: an assessment of movement coordination and coordination variability

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**Abstract:** Vector coding is a data analysis technique that quantifies inter-segmental coordination and coordination variability of human movement. The usual reporting of vector coding time-series data can be difficult to interpret when multiple trials are superimposed on the same figure. This study describes and presents novel data visualisations for displaying data from vector coding that supports multiple single-subject analyses. The dataset used in this study describes the lumbar-pelvis coordination in the transverse plane during a gait cycle. The data visualisation techniques presented in this study consists of the use of colour and data bars to map and profile coordination pattern and coordination variability data. The use of colour mapping provides the option to classify commonalities and differences in patterns of coordination between segment couplings and between individuals across a big dataset. Data bars display segmental dominance data that can provide an intuitive summary on coupling angle distribution over time. The data visualisation in this study may provide further insight on how people with adolescent idiopathic scoliosis perform goal-orientated movements following an intervention, which would support clinical management strategies.

## Introduction

Gait analysis research in the area of adolescent idiopathic scoliosis (AIS) typically involves the pooling of group data to report on the mean and standard deviation of several variables. However, seeking for an average performance between individuals provides no information about how any given individual has performed a task. Furthermore, individuals within a sample may respond in a positive or negative way to an intervention that can result in the group analysis revealing a ‘non-significant effect’. Alternatively, multiple single-subject analyses can supplement group research designs and help establish commonalities and differences both within and between individuals over repeated trials. This data analysis approach is known as ‘coordination profiling’[1] and when combined with advanced data visualisation techniques in vector coding, it is possible to compare empirical data across multiple segment couplings, participants, and experimental conditions.[2] Vector coding is a non-linear mathematical data analysis

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technique that quantifies movement coordination and coordination variability between segments of the body in a time domain.[2] In vector coding, the orientation between adjacent data points on an angle-angle diagram relative to right horizontal is calculated, which is referred to as the coupling angle that can range between 0-360° (Figure 1a). Each coupling angle across normalised time can be classified to a coordination pattern based on its polar position (Figure 1b).[2] While vector coding has been utilised in research on people with AIS,[3-5] frequency analysis was used that relates to the number of data points distributed within each coordination pattern classification over a normalised movement cycle. However, frequency analysis does not provide an accurate description on the coordination pattern if the distribution of the coupling angle continually changes within each coordination pattern classification.[2] In addition, Figure 1c clearly shows that mean coupling angle time-series data and associated coordination patterns would not be representative of several individuals. On the other hand, interpreting coupling angle and coordination variability data using a conventional format can be problematic when attempting to decode between time-series, particularly if multiple trials are overlapped on the same figure. Therefore, the aim of this study was to introduce vector coding and showcase novel visualisation techniques to present biomechanical data that supports multiple single-subject designs.

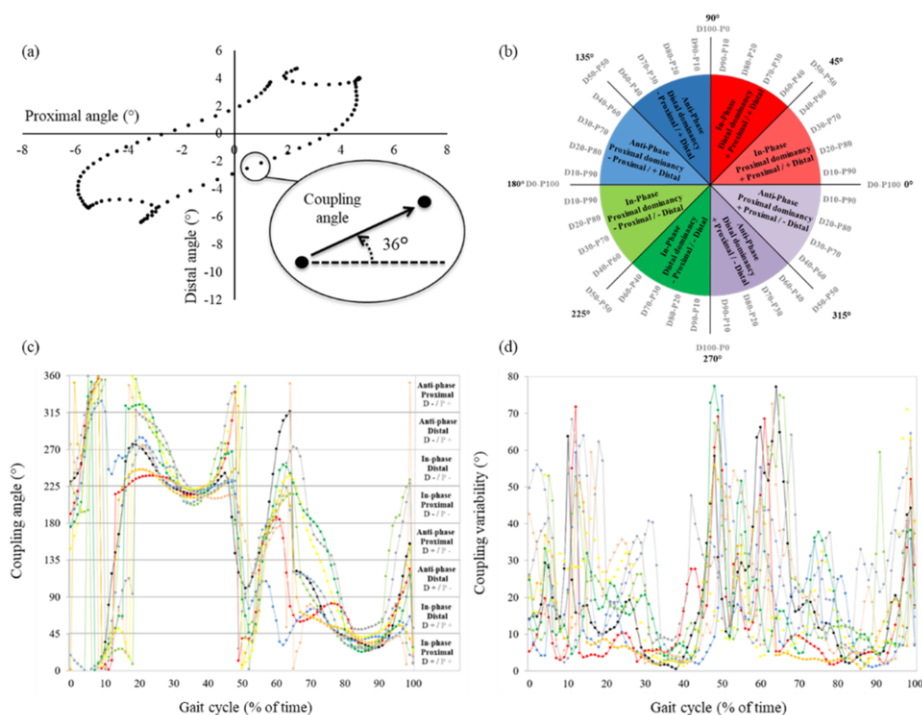


Figure 1. (a) Angle-angle diagram of pelvis (distal) - lumbar (proximal) coordination during the gait cycle in the transverse plane; insert is an example of one coupling angle (b) Coordination pattern classification<sup>2</sup> illustrating colour-scale for each classification. Segmental dominance (%) is shown around the circumference of the polar plot (grey text, D-distal/P-Proximal); (c) Individual coupling angle data on pelvis (distal) - lumbar (proximal) coordination during the gait cycle in the transverse plane; coupling angle data lies within a row that represents the associated coordination pattern classification (IPPD-in-phase proximal dominance, IPDD-in-phase distal dominance, APPD-anti-phase proximal dominance, APDD anti-phase distal dominance). (d) Individual coordination variability data on pelvis (distal) - lumbar (proximal) coordination during the gait cycle in the transverse plane.

Methods

Ten healthy males, with a mean age of 22.4 ( $\pm 2.46$ ) years, height of 180.3 ( $\pm 7.18$ ) cm and mass of 74.97 ( $\pm 11.02$ ) kg, participated in the study. Marker coordinate data over five trials was recorded at 100Hz using an eight-camera motion capture system (VICON, Oxford, UK). Two AMTI-OR6 force platforms (AMTI, Inc., Watertown, MA, USA) were used to assist in the identification of gait events. Lumbar and pelvis segment angles were processed in Visual3D (C-Motion, Inc., Germantown, MD, USA) using a low-pass Butterworth filter with a cut-off frequency of 6 Hz. For a detailed description on coupling angle and coordination variability calculations, coupling angle mapping, segmental dominance profiling, readers are directed to the following study.[2]

Results and Discussion

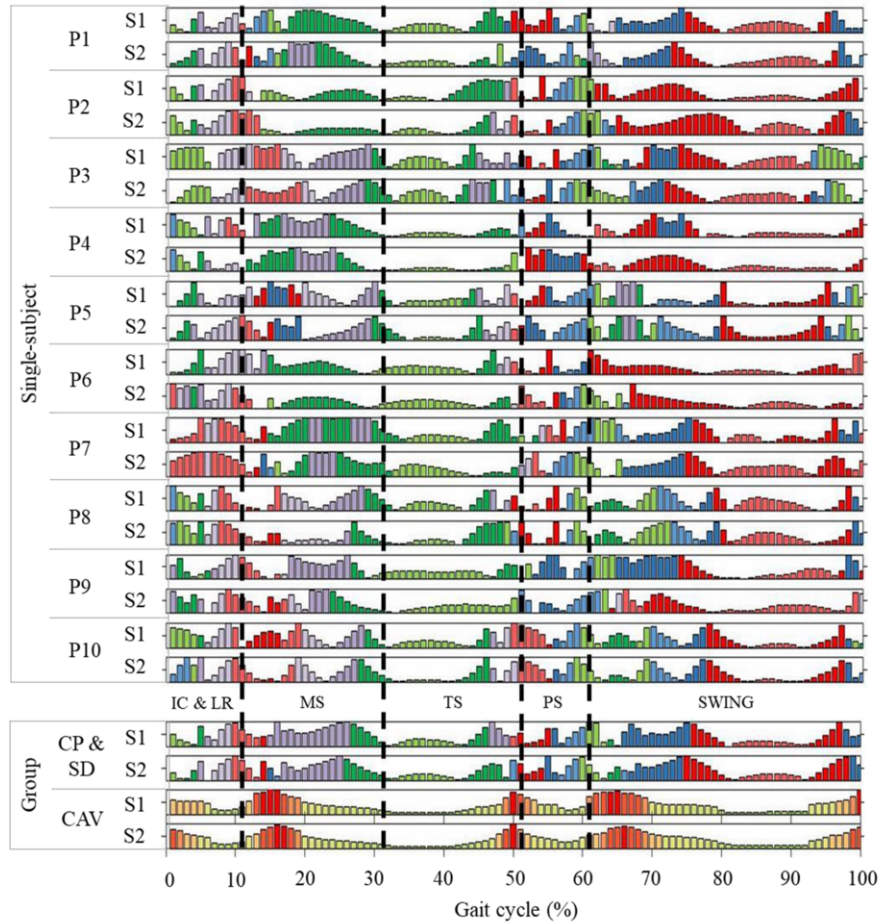


Figure 2. Coupling angle mapping (colour) and segmental dominance profiling (data bars) illustrating lumbar-pelvis coordination during gait in the transverse plane for 10 participants (P1-P10) and for the group across session one (S1) and session two (S2). Vertical dashed lines represent gait events based on group average (IC – initial contact / LS – loading response / MS – mid-stance / TS – terminal swing / PS – pre-swing / Swing phase). All data is time-series matched.

Figure 2 illustrates coupling angle mapping and segmental dominance profiling for session one (S1) and two (S2). This represents group mean lumbar-pelvis coordination in the transverse plane during a gait cycle. Coupling angle mapping effectively highlights the subtle differences in transitions between coordination patterns and between repeated measures (S1 versus S2). It is also important to note that similarities on group segmental dominance profiling across the gait cycle between S1 and S2 suggest similar coupling angle distributions. Comparisons are also evident between S1 and S2 regarding coordination variability mapping and profiling. High coordination variability between individual participants is noted during the transition between in-phase and anti-phase coordination or vice-versa.

Coupling angle mapping clearly shows differences between individuals and highlights the uniqueness of individual coordination patterns that questions the interpretation and clinical relevance of reporting on group mean data<sup>2</sup>. However, commonalities in lumbar-pelvis coordination during gait in the transverse plane between participants and between repeated measures were noted during terminal stance and through mid to late swing phase. The commonalities of in-phase coordination during these phases of the gait are expected since the maximal forward rotation of the pelvis contributes to step length of the lead limb, and that the pelvis precedes lumbar motion about the laboratory coordinate system towards the contra-lateral side. Also, the progressive decrease in pelvis segmental dominance and subsequent transition to lumbar segmental dominance profiles the time lag in segmental rotation between the segments during this in-phase coordination. Thus, segmental dominance profiling provides further interpretation on coordination at each instant in time than if the coupling angle were to be assigned to a single coordination pattern classification (i.e. in-phase, anti-phase, distal dominance, proximal dominance).

## Conclusion and Significance

This work presents coordination pattern, segmental dominance and coordination variability data via illustrations that provides distinctive insights into segmental movements that may support the design of individualised clinical interventions for people with AIS.

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# Concave or convex rod translation first in adolescent idiopathic scoliosis instrumentation with differential rod contouring?

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**Abstract:** The objective was to assess deformity correction and bone-screw force associated respectively with concave manipulation first, convex manipulation first, and different differential rod contouring configurations. Instrumentation scenarios were computationally simulated for 10 AIS cases with mean thoracic Cobb angle (MT) of  $54\pm 8^\circ$ , apical vertebral rotation (AVR) of  $19\pm 2^\circ$  and thoracic kyphosis of  $21\pm 9^\circ$ . Instrumentations with major correction maneuvers using the concave side rod were first simulated; instrumentations with major correction maneuvers using the convex side rod were then simulated. Simulated correction maneuvers were concave/convex rod translation followed by apical vertebral derotation and then convex/concave rod translation. There were no significant differences in deformity corrections and bone-screw forces between concave rod translation first and convex rod translation first with differential rod contouring. Increasing differential rod contouring angle and concave rod diameter improved AVR correction and increased the TK and bone-screw forces; the effect on the MT Cobb angle was not clinically significant.

**Keywords:** concave rod, convex rod, contour, computer simulation, bone-screw force, Cobb angle, derotation, translation

## Introduction

In adolescent idiopathic scoliosis (AIS) instrumentation, a commonly-used technique is to perform major correction maneuvers using the concave side rod before the convex side rod has been inserted. An alternative technique is to use the convex rod first.[1] Studies showed that deformity corrections were similar with the two techniques.[2,3] However, it is hypothesized that there would be significant difference in correction between the two techniques when differential rod contouring is used because of the significant difference in the rod contouring angle. Studies are yet to be conducted on the biomechanical differences between the two techniques. The objective was to assess deformity correction and bone-screw force associated respectively with concave manipulation first, convex manipulation first, and different differential rod contouring configurations.

## Methods

Instrumentation scenarios were computationally simulated for 10 AIS cases with mean thoracic Cobb angle (MT) of  $54 \pm 8^\circ$ , apical vertebral rotation (AVR) of  $19 \pm 2^\circ$  and thoracic kyphosis of  $21 \pm 9^\circ$ . Instrumentations with major correction maneuvers using the concave side rod were first simulated; instrumentations with major correction maneuvers using the convex side rod were then simulated. Simulated correction maneuvers were concave/convex rod translation followed by apical vertebral derotation and then convex/concave rod translation. The concave/convex rods were 5.5/5.5 and 6.0/5.5 mm diameter Co-Cr and contoured to  $35^\circ/15^\circ$ ,  $55^\circ/15^\circ$ ,  $75^\circ/15^\circ$ , and  $85^\circ/15^\circ$ , respectively. Corrections in the 3 anatomical planes and bone-screw forces were evaluated.

## Results and Discussion

Differences in simulated MT, TK, and AVR were less than  $5^\circ$  between concave and convex rod translation first; mean bone-screw force difference was less than 15N ( $P > 0.1$ ). Increasing differential contouring angle of 5.5/5.5 mm rods from  $35^\circ/15^\circ$  to  $85^\circ/15^\circ$ , the simulated MT changed from  $14 \pm 7^\circ$  ( $4-27^\circ$ ) to  $15 \pm 8^\circ$  ( $4-29^\circ$ ), AVR from  $12 \pm 4^\circ$  ( $6-19^\circ$ ) to  $6 \pm 5^\circ$  ( $0-15^\circ$ ), TK from  $23 \pm 4^\circ$  ( $18-29^\circ$ ) to  $42 \pm 4^\circ$  ( $37-48^\circ$ ) (Figure 1), and bone-screw forces from  $159 \pm 88\text{N}$  to  $329 \pm 170\text{N}$  ( $P < 0.05$ ). Increasing the concave rod diameter from 5.5 to 6 mm, the mean MT correction improvement was less than  $2^\circ$ , the AVR correction was improved by  $2^\circ$ , the TK increased by  $4^\circ$ , and bone-screw force increased by about 25N ( $P < 0.05$ ).

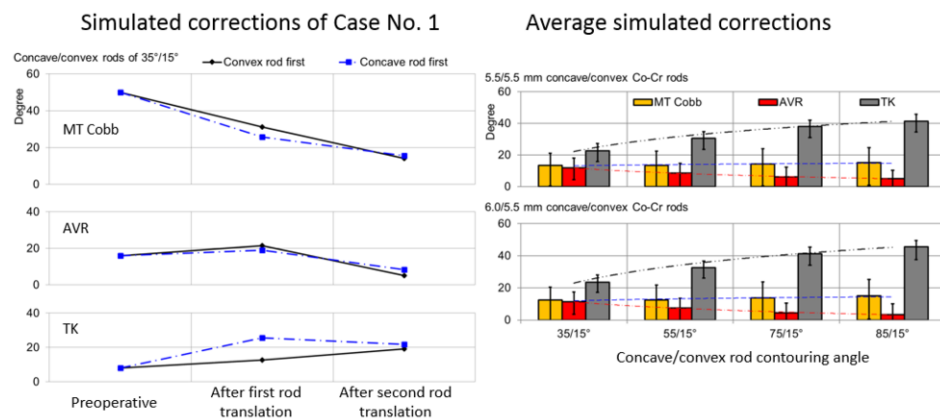


Figure 1. Simulated corrections of the main thoracic (MT) Cobb, apical vertebral rotation (AVR), and thoracic kyphosis (TK)

## Conclusion and Significance

There were no significant differences in deformity corrections and bone-screw forces between concave rod translation first and convex rod translation first with differential rod contouring. Increasing differential rod contouring angle and concave

rod diameter improved AVR correction and increased the TK and bone-screw forces; the effect on the MT Cobb angle was not clinically significant.

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# Chapter 7

## Conservative Treatment: Casting

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# Comparison of two types of casting in early-onset scoliosis

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**Abstract:** Early-onset scoliosis (EOS) can be a progressive and debilitating condition if left untreated. Different casting techniques have fallen in and out of favor over the years for conservative management. Two types of casting, elongation-derotation-flexion (EDF) and body casting (BC) are employed at our institution. Here we compare the radiographic outcomes between these two types of casting in a cohort of patients diagnosed with EOS. Sixteen children with EOS were treated by EDF serial casting while seventeen children with the same diagnosis were treated by BC. Radiographic measurements included Cobb angle, rib-vertebral-angle difference (RVAD) and vertebral rotation (VR) by Nash-Moe method in casting (IC) or out of casting (OOC), thoracic height (TH) and width (TW). All of the patients had x-ray measurements at pre-casting OOC, 1<sup>st</sup> IC and final post-casting OOC. Casts were changed every 2-4 months. Independent two sample t-test, Wilcoxon rank-sum test, and Chi-square test were performed. There were no significant differences at the initial treatment for age, classification of EOS, OOC, RVAD, VR, kyphosis, TH, and TW between EDF and BC casting. There were no significant differences of changes for OOC, RVAD, VR, kyphosis, TH and TW from pre-casting to the final post-casting status between two casting techniques ( $P>0.05$ ). However, children with EDF tended to receive 3 to 4 more castings than those with BC (7.5 vs.4 casts) ( $P=0.007$ ) and achieved better outcomes in success (25% vs.20%) and improvement (50% vs.10%) ( $P=0.03$ ). EDF has better outcomes with EOS improvement when there is treatment of longer duration.

**Keywords:** Early-onset scoliosis; elongation-derotation-flexion (EDF) casting; body casting

## Introduction

Although the true prevalence of early-onset scoliosis (EOS) is currently unknown, they are inhomogeneous patients, including idiopathic EOS (<1%), congenital anomalies, neuromuscular diseases, and scoliosis-associated syndromes (neurofibromatosis).[1] A scoliotic spine will generally continue to grow along its deformed axis unless intervened upon,[2] and the early presentation of EOS would mean the child would continue to propagate their deformity through their entire adolescence. This ultimately can lead to significant, debilitating spinal deformity at an adult age. Another worry is that because lung alveolar development happens primarily after birth and into childhood,[3] scoliosis that is present throughout infancy and childhood could lead to significant chest wall restriction and not allow proper cardiopulmonary development.[4]

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Recent research has brought the use of casting back into the conversation of treatment for EOS. In 1964 a casting technique was described by Cotrel and Morel, called elongation-derotation-flexion (EDF); the idea of which was to apply correcting forces to the deformed spine, held by casting, along all three axes of the spine.[5] This method requires the use of a special table, now called an AMIL frame, which is used to apply the elongation, derotation and flexion forces; the position is then held while a plaster cast is applied.[6]

Then, from 1975-2000, Prof. Min Mehta from the UK used this same casting technique on 136 children with EOS with remarkable results.[7] Prof. Mehta distributed her patients into 4 separate groups. Two of the groups were assigned based upon build; either a sturdy build with good muscle mass and tone, or a slender build in which the child had less muscle tone and bulk and more joint laxity. She also categorized whether children were diagnosed with a known congenital syndrome (Rett's, Prader-Wili, Larsen's, e.g.), or children with an obvious, but un-diagnosable syndrome (multiple congenital malformations or deformities). The results of Prof. Mehta's study showed that 94 of the 136 children had a complete resolution of their scoliosis and required no further surgery or treatment. The 42 other children had reduction in their scoliosis but were unable to obtain complete resolution of their deformity. Prof. Mehta uncovered a few key differences between the complete resolution group (group 1), and the others (group 2), the biggest determinant being age of diagnosis and treatment. She found that the mean age of starting treatment for group 1 to be 19 months, compared to 30 months for group 2, and concluded that the average 1-year delay in treatment for these children made a large difference in the ability of the EDF casting to correct their deformity. This is largely due to an extra year of growth the children in group 2 had, which further exacerbated their deformity – a theory supported by looking at the mean Cobb angle at the start of treatment in both groups; 32° (11°-65°) in group 1 compared to 52° (23°-92°) in group 2. Additional work done by Dr. Sanders et al. further confirmed these results in a separate study on EDF casting, finding that infants are largely cured of their scoliosis if treatment is begun within the first 20 months of life, have a Cobb angle of less than 60°, and if their scoliosis is idiopathic and not the result of a congenital syndrome.[8]

Based on this, it is clear that EDF casting is an effective and reasonable form of conservative treatment for EOS. In the literature it has been shown to have the same or better outcomes when compared to invasive treatment and with less complications. However, there is currently a lack of studies comparing the effectiveness of EDF casting to other forms of casting. It would be useful to know whether these results are superior to those of other casting alternatives, such as body casting (BC). BC employs the same principles of EDF casting with the same corrective forces applied to the spine while casting. The main differences are that BC utilizes a hip spica table to position the patient versus a AMIL frame with EDF, and the corrective forces in BC are largely applied by hand. Given these differences in technique, it is not reasonable to assume they achieve the same outcomes without proper evaluation. We aim to compare these two types of casting techniques based on radiographic outcomes: 1) To compare changes in Cobb angle, rib-vertebral-angle difference (RVAD) and vertebral rotation (VR) by Nash-Moe method in casting (IC) or out of casting (OOC), thoracic height (TH) and width (TW) between EDF and BC casting for minimal 6 months follow-up; 2) To compare these changes from pre-casting OOC to final post-casting OOC within EDF or BC group; 3) To determine success and improvement rate for EOS.

## Methods

The study is a retrospective chart review. Using Epic software installed at Children's Hospital of Wisconsin (CHW), we reviewed medical records of patients seen in the CHW Orthopaedics Department. Patients reviewed must have met criteria for inclusion. These criteria included a diagnosis of early-onset scoliosis, treatment of the condition with serial EDF casting or BC, and at least 6 months of follow-up on record. Status of course of treatment at last follow-up was recorded. Other data collected included: age at first treatment, sex, Cobb Angle, AVR, and RVAD as determined by radiograph; time between detection and referral for treatment, number of castings, duration of casting, and complications reported.

As stated, two different types of casting techniques are employed at CHW in the treatment of EOS. For EDF, patients are given general anesthesia and intubated. They are positioned supine on the AMIL frame with one strap on each iliac crest and applying an inwardly oblique downward pulling force (see Figure 1). There is an occipitomenal strap applying a pulling force in the rostral direction, completing the traction and elongation portion. The patient wears a cast shirt and have a few layers of padding to avoid cast irritation. Once plaster of Paris is applied, the physician will manually apply pressure to the posterolateral aspect of the convex curve in an anterior direction. They will also hold the contralateral hip and concave curve in place while the plaster dries. Once the plaster of Paris has dried, a large hourglass-type hole is cut anteriorly into the cast to allow for more natural movement of the thorax and abdomen. Another smaller cut is made posterolaterally over the concavity of the curve to allow for expansion of the rib cage.

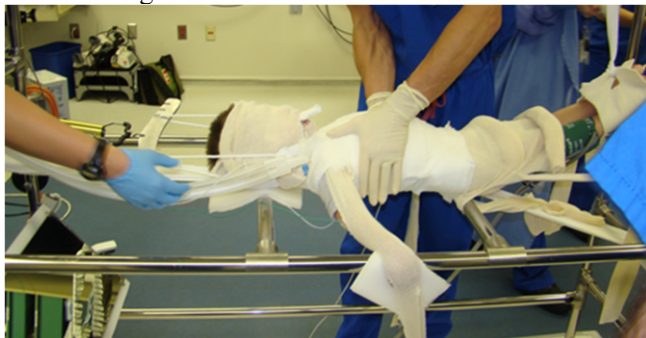


Figure 1. A special table, called an AMIL<sup>®</sup> frame, is used to apply the elongation, derotation, and flexion forces; the position is then held while a plaster cast is applied. Casting technique is described by Cotrel and Morel and modified by Mehta.

In body casting, the patient is prepared for the procedure in a similar fashion. They are put under general anesthesia then positioned supine on a hip spica table. Padding is placed on the patient in a similar manner to EDF. Traction is applied manually to the head and feet by members of the surgical team (see Figure 2). Manual derotation and flexion forces are employed while applying the plaster of Paris and allowing the cast to set.



Figure 2. A hip spica table is used to position the patient while elongation, derotation, and flexion forces are applied manually. The position is then held while a cast is applied.

A total of 56 patients that underwent serial casting were found in the initial database search. After review for exclusion criteria, a total of 33 remained for study. Sixteen children with EOS were treated by EDF serial casting at a mean age of 23 months (10 to 36). Seventeen children with the same diagnosis were applied by BC at a mean age of 20 months (6 to 38). All of them had x-ray measurements at pre-casting OOC, 1<sup>st</sup> IC and final post-casting OOC. Status of the curve after treatment was categorized per Scoliosis Research Society guidelines as correction, stabilization, or progression. Casts were changed every 2-4 months. Independent two sample t-test (Pooled or Satterthwaite) and Wilcoxon rank-sum test were used for two groups comparison. Chi-square test was performed for an association of variables. Paired t-test was applied for within group differences of variables.

## Results and Discussion

The mean follow-up was 15 months (2.5 to 36). Between the two groups EDF and BC, there were no significant differences at the initial treatment for age, classification of EOS, OOC Cobb angle, RVAD, VR, kyphosis, TH, and TW between EDF and BC casting. Statistical analysis revealed that there were no significant differences of changes for OOC Cobb angle (see Figure 3), RVAD, VR, kyphosis, TH and TW from pre-casting to the final post-casting status between two casting techniques ( $P > 0.05$ ). However, children with EDF tended to receive 3 to 4 more castings than those with BC (7.5 vs. 4 casts) ( $P = 0.007$ ) and achieved better outcomes in success (25% vs. 20%) and improvement (50% vs. 10%) ( $P = 0.03$ ). Table 1 presented changes of radiographic measurements from pre-casting to final post-casting status within EDF or BC group.

### Casting Outcomes as Measured by Primary Cobb Angle Between Group Change with 1st Casting and Final change OOC

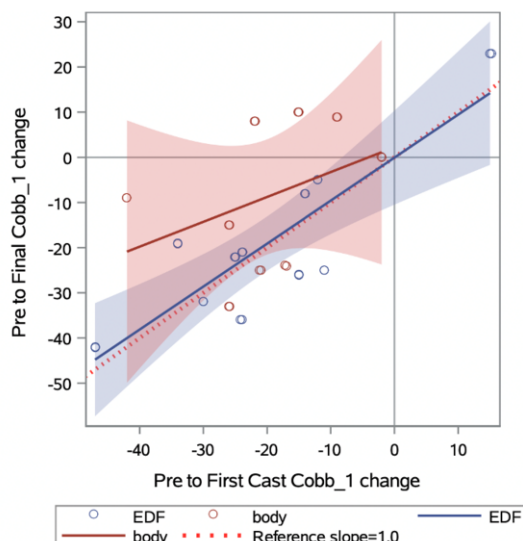


Figure 3. While both EDF and BC groups showed statistically significant reduction in primary OOC Cobb angle, neither group was found to be statistically superior to the other.

Table 1. Changes in radiographic measurements from pre-casting to final post-casting within EDF casting or Body Cast (Mean±SD, n=17 for EDF, n=17 for BC, P-value)

Variables	Pre-casting Mean±SD	In-casting Mean±SD	Post-casting Mean±SD
EDF major Cobb (°)	53.7±17.9	37.4±18.0**	33.3±22.4***
BC major Cobb (°)	50.0±17.6	29.6±11.5***	35.4±20.9
EDF RVAD (°)	28.2±23.3	26.1±25.9	18.1±25.7*
BC RVAD (°)	23.2.1±17.2	19.4±15.0	14.7±12.6
EDF VR (0-4)	2.2±1.0	2.0±1.1*	1.6±1.3*
BC VR (0-4)	1.9±0.9	1.8±0.9	1.7±1.0
EDF TH (cm)	135.9±8.5	150.2±8.3*	156.8±13.6**
BC TH (cm)	135.4±15.5	131.3±17.7	148.9±16.2*
EDF TW (cm)	84.4±5.0	90.1±7.8**	93.8±7.3***
BC TW (cm)	85.1±8.9	75.8±14.9	90.5±10.9**

Note: \* P<0.05; \*\* P<0.01; \*\*\* P<0.001 when compared in-casting or post-casting with pre-casting.

### Conclusion and Significance

Our results indicate that BC accomplishes much of the same reduction in major Cobb angle, RVAD, and vertebral rotation as that of EDF casting for patients with EOS. It also equally improves thoracic width and thoracic height in this population. However, when patients are treated with EDF serial casting for a longer duration than their BC counterparts, there are improved outcomes. According to several studies including one done by Fedorak et. al., the greatest potential for correction with casting occurs prior to 2 years of age. Even taking short cast holidays significantly reduces outcomes compared to no cast holidays.[9] This makes intuitive sense, and it follows that the longer a child is casted with EDF during this critical growth period, the better long-

term outcomes achieved. The results found in our study indicate significant clinical impact. First, if both casting modalities improve EOS to a similar degree within the same time period, then BC may be just as viable, and the choice may be left to the clinician. It may even be preferred given lack of specialized equipment and ease of the procedure, allowing for less time under general anesthesia. Of course, contrasting this is the point that EDF shows improved outcomes in longer treatment duration. This indicates that EDF should be preferred in patients with severe spinal curves requiring prolonged treatment, as it may be more effective at reducing curves in the long term. Limitations to this study include sample size and that patients with BC are more likely to have shorter follow-up than those with EDF.

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# Chapter 8

## Conservative Treatment: Bracing

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# The impact of immediate in-brace 3D corrections on curve evolution after two years of treatment: preliminary results

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**Abstract:** For the brace treatment of adolescent idiopathic scoliosis (AIS), in-brace correction and brace-wear compliance are well-documented parameters associated with a greater chance of treatment success. However, the number of studies on the impact of sagittal and transverse correction on curve evolution in the context of bracing is limited. The objective of this work was to evaluate how immediate in-brace correction in the three anatomical planes is related to long-term curve evolution after two years of bracing. We performed a retrospective analysis on 94 AIS patients followed for a minimum of two years. We analyzed correlations between in-brace correction and two-year out-of-brace evolution for Cobb and apical axial rotations (ARs) in the medial thoracic and thoraco-lumbar/lumbar regions (MT & TL/L). We also studied the association between the braces' kyphosing and lordosing effect and the evolution of thoracic kyphosis (TK) and lumbar lordosis (LL) after two years. Finally, we separated the patients into three groups based on their curve progression results after two years (corrected, stable and progressed) and compared the 3D in-brace corrections and compliance for each group. Coefficients were statistically significant for all correlations. They were weak for Cobb angles (MT: -0.242; TL/L: -0.275), low for ARs (MT: -0.423; TL/L: -0.417) and moderate for sagittal curves (TK: 0.549; LL: 0.482). In-brace coronal correction was significantly higher in corrected vs stable patients ( $p=0.004$ ) while compliance was significantly higher in stable vs progressed patients ( $p=0.026$ ). This study highlights the importance of initial in-brace correction in all three planes for successful treatment outcomes.

**Keywords:** bracing, 3D correction, curve evolution, brace-wear compliance

## Introduction

Bracing is the most common form of conservative treatment prescribed to patients with moderate scoliosis ranging from 25 to 40°.[1] There is strong evidence that initial in-brace correction in the coronal plane as well as brace-wear compliance help prevent curve progression and are therefore associated with higher chance of treatment success.[2,3] However, adolescent idiopathic scoliosis is a three-dimensional deformity, yet there is still only a limited amount of bracing studies that have investigated anatomical planes other than the coronal.

Our group has been designing thoracolumbosacral orthoses (TLSOs) using the computer-aided design and manufacturing (CAD/CAM) approach, where a topography

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surface scan is taken from the patient and modified by an experienced orthotist in a CAD software, before being exported to a numerical milling machine carving a positive mold for subsequent thermoforming. In a previous randomized controlled trial, we added refinement steps using a personalized finite element model built from 3D reconstructions of the spine, ribcage and pelvis made from biplanar radiographs.[4,5] Orthotists were able to simulate the donning and tightening of the brace, and iteratively improve the coronal in-brace correction while reducing surface area covered and weight, all before manufacturing. Previous studies have shown the validity of such an approach, and overall, the use of these numerical tools allows the study of in-brace corrections and curve evolution in all three anatomical planes.[4,6] Sagittal alignment and transverse plane rotations may play a significant role in treatment success,[7] but no study has yet evaluated the long-term impact of modifying them in-brace on the 3D deformity.

The objective of this work was to study how immediate in-brace correction in the three anatomical planes is related to long-term curve evolution after two years of bracing.

## Methods

Ninety-four AIS patients, adhering to SRS standardized bracing criteria [1] and followed for a minimum of two years, were retrospectively studied. All cases received a TLSO brace designed using the previously described CAD/CAM approach, some with added FEM refinements, some without. The patients were not differentiated based on the addition of FEM simulations.

Biplanar radiographs and corresponding 3D reconstructions were taken at three timepoints: the initial visit (presenting deformity, out of brace), at brace delivery (in-brace), and at the two-year visit (out of brace). Immediate in-brace corrections of main thoracic (MT) and thoracolumbar/lumbar (TL/L) Cobb and apical axial rotations (AR) (MT, TL/L) were calculated at brace delivery to the patient. The in-brace modification of T4-T12 thoracic kyphosis (TK) and L1-L5 lumbar lordosis (LL) was also assessed. The out-of-brace evolution of each measurement was measured at the two-year visit. Compliance was tracked over the studied period using temperature-logging sensors.

First, we analyzed the correlations between in-brace correction and two-year out-of-brace evolution for Cobb (coronal) and ARs (transverse) in MT and TL/L by fitting a linear regression and extracting the Pearson coefficient and the p-value to characterize the strength of the association.[8] In the sagittal plane, we separated the patients in subgroups based on their presenting initial alignment: hypo-kyphotic (under 20° TK), normo-kyphotic (20-40° TK) and hyper-kyphotic (over 40° TK); hypo-lordotic (under 40° LL), normo-lordotic (40-60° LL) and hyper-lordotic (over 60° LL). Sagittal linear regressions were calculated for all cases as well as individual subgroups.

We also separated the patient cohort into three subgroups based on their curve progression results after two years: cases corrected  $> 5^\circ$ , stable cases  $\pm 5^\circ$ , and cases that progressed  $> 5^\circ$ . SRS criteria classifies the first two subgroups as successful and the last one as failed. The immediate in-brace corrections in coronal and transverse, the in-brace sagittal curve modifications, and the average daily brace wear were compared for the three subgroups by performing individual one-way ANOVAs (95% significance level) for every parameter using MATLAB R2020a software (MathWorks, USA). The analysis was performed for the MT region, then the TL/L one.

## Results and Discussion

Table 1. Regression coefficients using the out-of-brace two-year evolution of the measurement as a dependent variable, in the three anatomical planes for all 94 patients; significant p-values ( $< 0.05$ ) are marked with \*

Plane	Measurement	Independent variable	r coefficient	P-value
<b>Coronal</b>	MT Cobb	In-brace correction	-0.242	0.02*
	TL/L Cobb	In-brace correction	-0.275	0.008*
<b>Transverse</b>	MT apical axial rotation	In-brace correction	-0.423	$< 0.001^*$
	TL/L apical axial rotation	In-brace correction	-0.417	$< 0.001^*$
<b>Sagittal</b>	T4-T12 thoracic kyphosis	Brace kyphosing effect	0.549	$< 0.001^*$
	L1-L5 lumbar lordosis	Brace lordosing effect	0.482	$< 0.001^*$

Coronal correlations were weak but statistically significant (Table 1). Transverse correlations were low but significant, hinting that the in-brace correction of ARs was associated with a 2-year decrease in transverse plane vertebral rotation. Braces' kyphosing and lordosing effects were positively associated with the 2-year evolution, with low-to moderate ( $r \sim 0.5$ ) highly significant correlations ( $p < 0.001$ ). Separating the sagittal measurements into subgroups (Table 2), the normo- group displays moderate significant positive correlations ( $r > 0.5$ ) representative of the overall trend for the 94 patients. Only the hyper-kyphotic group shows a strong correlation ( $r > 0.7$ ), an association not seen in the lumbar region, hinting that the target brace reduction of kyphosis was achieved and linked to a better sagittal thoracic alignment after 2 years in these patients. Hypo- cases in the thoracic and lumbar regions did not show any significant correlation, suggesting that the target increase of sagittal curves in-brace does not necessarily translate to the desired alignment long term.

Table 2. Regression coefficients for out-of-brace two-year evolution vs brace effect in the sagittal plane for hypo-, normo- and hyper- subgroups; significant p-values ( $< 0.05$ ) are marked with \*

Measurement	Subgroup	r coefficient	P-value
<b>Thoracic Kyphosis</b>	Hypo-kyphotic	0.015	0.949
	Normo-kyphotic	0.526	$< 0.001^*$
	Hyper-kyphotic	0.750	0.003*
<b>Lumbar Lordosis</b>	Hypo-lordotic	0.500	0.141
	Normo-lordotic	0.556	$< 0.001^*$
	Hyper-lordotic	0.129	0.567

Overall, the extracted regressions were more significant and displays higher coefficient than other similar studies such as the one by Kwan et al.,[9] and a higher statistical significance that could be linked to the greater number of patients analyzed (94 in our study vs 46 in theirs).

When separating the patient cohort into corrected, stable and progressed subgroups (Figure 1), only the coronal correction of Cobb angle was a significant in-brace metric able to differentiate between the curve progression subgroups in the equivalent region. In-brace correction was significantly higher for patients that were corrected (improved  $> 5^\circ$ ) after two years compared to the stable and the progressed groups, between which there was no difference. Inversely, compliance was significantly higher for the stable group compared to the progressed ones ( $p = 0.026$ ) while corrected patients show an increased level of daily brace-wear that was not statistically significant ( $p = 0.110$ ). Based on our results, higher brace-wear compliance seems to differentiate patients that progress vs the ones that stay controlled while greater in-brace correction differentiates patients that get corrected long-term with the rest.

These results are in line with numerous studies that highlight the importance of coronal in-brace correction and compliance for curve progression.[10-12] Chalmers described how the amount of coronal in-brace correction could predict the probability of a patient to be in an improved, neutral or progressed subgroup, highlighting that high in-brace corrections could be promoting curve improvement over time.[12] In the sagittal plane, Matsumoto et al.[7] reported increased risk of progression for several types of abnormal sagittal alignment. Based on our results, a targeted brace-induced modification of the sagittal curves could be correlated to a corresponding better long-term sagittal alignment, in certain types of patients. Our transverse plane measurements did not discriminate between progressive and non-progressive patients unlike in Kwan et al.'s study,[9] in which the reported significance was low ( $p = 0.049$ ). Courvoisier also highlighted the importance of transverse plane parameters for predicting curve progression,[13] but the significance of the reported trends in the brace treatment was tempered by the high variability in the results.[14]

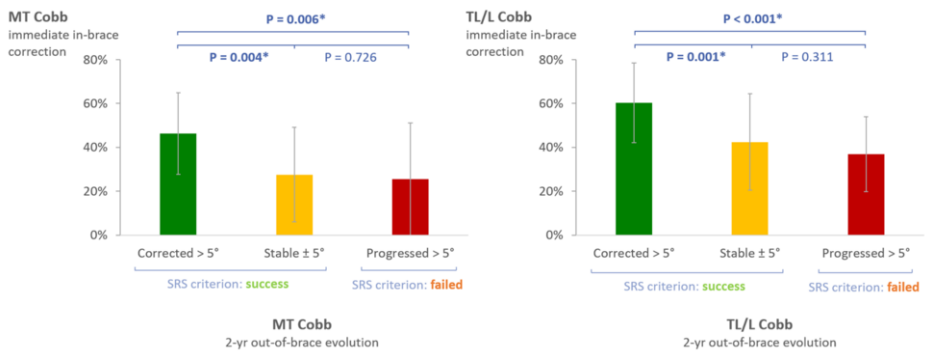


Figure 1 – Average immediate in-brace correction for patients according to their outcome after two years (corrected, stable or progressed); error bars show  $\pm$  std; a positive value means a correction of the curve; statistically significant p-values ( $p < 0.05$ ) marked with \*.

Conclusions and Significance

Higher coronal in-brace correction and compliance differentiated between corrected, stable and progressed patients after two years of treatment. Brace action in the sagittal and transverse planes was associated with a similar evolution of the out-of-brace measurements after two years. Overall, this study highlights the importance of initial in-brace correction in all three planes for successful treatment outcomes.

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# Back muscle function in adolescent girls treated with a rigid brace for idiopathic scoliosis: no impact of 6-month brace wear on muscle strength or endurance

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**Abstract:** The study aimed to determine the impact of 6-month rigid brace on back muscle strength and endurance in adolescents with idiopathic scoliosis. Sixty-one girls, aged 7.0–16.0, were analyzed in two groups: the study group (6-month rigid brace wear) vs. the control group (no brace treatment), recruited consecutively and matched for age, body height, weight, BMI, primary curve location and Cobb angle. All patients underwent clinical and radiological examination, modified Biering–Sorensen test, prone and standing maximum strength and endurance tests. No significant difference between groups in back muscles strength or endurance, both global and reported to body weight was found. No relation between the daily brace time and the back muscle strength or endurance was observed. The 6-month use of a rigid brace did not affect the strength or endurance of the back muscles in adolescent girls treated for idiopathic scoliosis.

**Keywords:** idiopathic scoliosis, muscle endurance, muscle strength, rigid brace

## Introduction

The bracing is considered the treatment of choice in skeletally immature idiopathic scoliosis (IS) patients with Cobb angle between 25° and 40°. A possible negative effect of a rigid brace on the torso muscle's function has been raised.[1-5] A literature review showed insufficient evidence of whether the rigid brace can negatively impact the back muscle strength or endurance during prolonged treatment of IS patients. Schreiber et al.[6] underlined the need for a study comparing IS patients treated with a brace versus IS patients without a brace. The study aimed to determine the impact of 6-month rigid brace treatment on the back muscle strength and endurance in adolescent girls with IS.

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## Methods

### *Materials*

Sixty-one females with IS, mean age  $13.5 \pm 1.7$  (7.0–16.0), were included consecutively in either the study or the control group. The study group's inclusion criteria were: female patients aged 7–16 years with IS, having been treated with a rigid brace for at least six months. The control group's inclusion criteria were: female patients aged 7–16 years with IS, without brace treatment, or just before the brace. Informed consent was obtained from patients and their parents/legal guardians.

The study group consisted of 30 patients treated with Cheneau rigid brace (N=30); the control group consisted of 31 patients with no brace treatment (N=31). According to the declared daily brace wearing time the patients were categorized as: night time rigid brace (8–12 hours per day - wearing a brace mainly in bed, N=15), part time rigid brace (12–20 hours per day - wearing a brace mainly outside the school and in bed, N=9) and full time rigid brace (20–24 hours per day - wearing a brace all the time, N=6).[7]

The groups were matched for standing body height, sitting body height, weight, BMI, Cobb angle, primary curvature location, number of primary curvature vertebrae (Table 1.).

Patients from both groups performed PSSE as an integral part of scoliosis treatment.

### *Methods*

The clinical examination consisted of the body weight, standing and sitting body height measurements. The radiological examination was performed based on standing antero-posterior long-cassette radiograms. The localization, the Cobb angle, and declared daily bracing wear time were noted.

Patients were subjected to the following muscles tests: modified Biering–Sorensen test, prone and standing maximal muscular strength or endurance tests. The tests were performed using a portable digital dynamometer (model FB5k, Axis, Poland).

### *Modified Biering–Sorensen test*

The patient was in a prone position on the examination table (Figure 1.A.). The examiner lowered the headrest. The patient was asked to keep the torso in a horizontal position as long as possible (Figure 1.B.). The test was ended when the patient touched with the trunk the elastic band, situated 10 cm below. The results were measured in seconds.

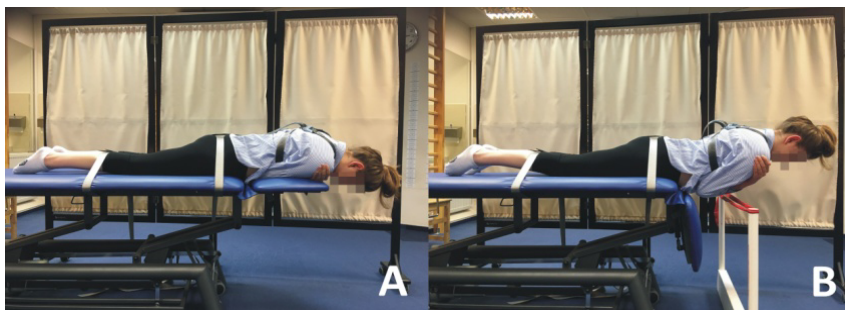


Figure 1. Modified Biering–Sorensen test: A – the starting position, B – the patient during the test.

### *Prone maximal strength test*

The starting position was the same as for the modified Biering–Sorensen test (Figure 2.A.). The patient was wearing a harness. A dynamometer's external sensor was fixed between the table and the harness by a non-elastic belt. The patient was asked to perform trunk extension with maximum force (Figure 2.B.). The peak of force value was recorded in newtons.

### *Prone endurance test*

The starting position was the same as for the prone maximal strength test. The patient was asked to extend the trunk with 70% ( $\pm 20\%$ ) of the maximal strength and maintain as long as possible (Figure 2.C.). The meter was placed at the level of the patient's eyes for the control of the force value. When the patient approached the strength tolerance value, it was signaled by a sound effect. The time was recorded in seconds.

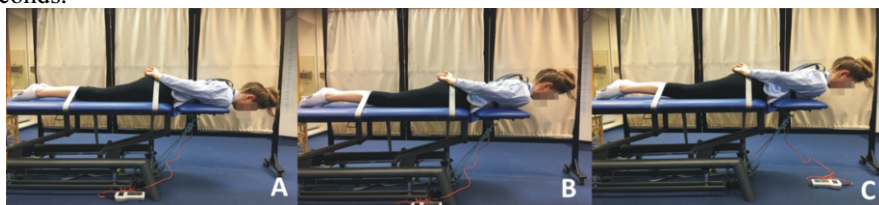


Figure 2 Prone maximal strength test or prone endurance test: A – the starting position, B – prone maximal strength test, C – prone endurance test.

### *Standing maximal strength test*

The starting position was standing facing a wall bar (Figure 3.A.). The patient was wearing a harness. The pelvis was fixed, the dynamometer's external sensor was fixed between the wall bar and the harness at the patient's sternum level by a non-elastic Belt. The patient was asked to perform trunk extension with maximum force (Figure 3.B.). The peak of force value was recorded in newtons.

### *Standing endurance test*

The starting position was the same as for the standing maximal strength test. The patient was asked to extend the trunk with 70% ( $\pm 20\%$ ) of the maximal strength and maintain as long as possible (Figure 3.C.). The meter was placed at the level of the patient's eyes for the control of the force value. When the patient approached the



strength tolerance value, it was signaled by a sound effect. The time was recorded in seconds.

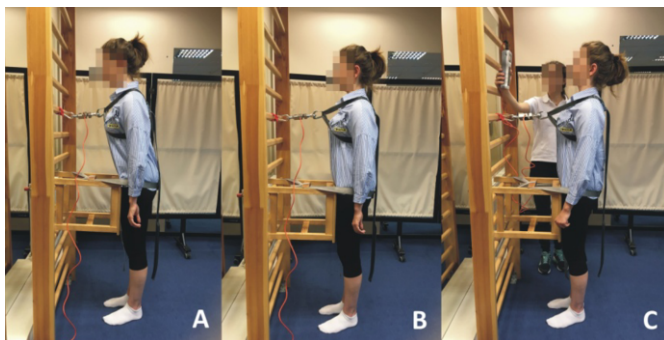


Figure 3. Standing maximal strength test or standing endurance test: A – the starting position, B – standing maximal strength test, C – standing endurance test.

### Data analysis

The statistical analysis was performed using Statistica 13.1 (TIBCO Software Inc., Poland). The level of significance was established at  $p < 0.05$ .

## Results and Discussion

No significant difference between groups in back muscles strength or endurance was found: the modified Biering–Sorensen test ( $p=0.6392$ ), prone maximal strength test ( $p=0.4439$ ), standing maximal strength test ( $p=0.1486$ ), prone endurance test ( $p=0.9942$ ) and standing endurance test ( $p=0.8231$ ) (Table 2.)

No significant difference between groups in back muscles strength or endurance value reported to the body weight was found: the modified Biering–Sorensen test ( $p=0.3231$ ), prone maximal strength test ( $p=0.9311$ ), standing maximal strength test ( $p=0.4168$ ), prone endurance test ( $p=0.6916$ ) and standing endurance test ( $p=0.6810$ ) (Table 2.)

In the study group, no significant relation was observed between the Cobb angle and the back muscle strength or endurance test results.

In the control group, a significant negative correlation was found between the prone and the standing maximal strength test reported to the body weight and the Cobb angle ( $r=-0.53$ ,  $p=0.0021$ ) and ( $r=-0.47$ ,  $p=0.0074$ ) respectively.

In both groups, no significant relation between the primary curvature location (thoracic/thoracolumbar/lumbar) and muscle strength or endurance test results was found.

In the study group, no significant relation between daily bracing time (full time/part time/night time) and the strength or the endurance test results was found: modified Biering–Sorensen test ( $p=0.4953$ ), prone maximal strength tests ( $p=0.4461$ ), standing maximal strength tests ( $p=0.2510$ ), prone endurance test ( $p=0.5937$ ) and standing endurance test ( $p=0.5635$ ).

**Table 1. Anthropometric Data and the Characteristics of Scoliosis in Both Groups**

	Study group N = 30	Control group N = 31	p value
Age [years]	13.6 ± 1.3 (11.0 – 16.0)	13.4 ± 2.0 (7.0 – 16.0)	0.9712 <sup>a</sup>
Standing body height [cm]	161.7 ± 7.9 (147.0 - 176.0)	159.2 ± 10.7 (120.0 - 171.0)	0.7238 <sup>a</sup>
Sitting body height [cm]	84.8 ± 4.2 (76.0 - 94.0)	83.1 ± 5.5 (65.0 - 90.0)	0.3634 <sup>a</sup>
Body weight [kg]	49.8 ± 8.3 (34.0 - 67.5)	47.5 ± 10.8 (20.0 - 69.0)	0.3374 <sup>a</sup>
Body Mass Index	18.96 ± 2.43 (14.81 – 24.20)	18.49 ± 2.97 (12.21 – 25.94)	0.5011 <sup>b</sup>
Primary curvature location	Thoracic: 16 Thoracolumbar: 7 Lumbar: 7	Thoracic: 14 Thoracolumbar: 6 Lumbar: 11	0.5819 <sup>c</sup>
Number of primary curvature vertebrae	7 ± 2	6 ± 1	0.9655 <sup>a</sup>
Cobb angle [°]	31.0 ± 9.0	31.0 ± 10.0	0.9712 <sup>a</sup>

Note: The table shows the average values and standard deviation, the minimum, and the maximum values are given in brackets. For the primary curvature location, the number of patients was given. For the number of primary curvature vertebrae and the Cobb angle, mean values and standard deviation are given. a - U - Mann - Whitney, b-t-Student, c - Chi<sup>2</sup>.

**Table 2. The Results of the Modified Biering-Sorensen Test, Prone Maximal Strength Test, Prone Endurance Test, Standing Maximal Endurance Test and Standing Endurance Test**

	Study group N=30	Control group N=31	p value
Modified Biering–Sorensen test [s]	196 ± 91 (70–486)	191 ± 57 (66–307)	0.6392 <sup>a</sup>
Prone maximal strength test [N]	281.6 ± 97.3 (118.4–552.8)	263.0 ± 90.7 (83.8–441.0)	0.4439 <sup>b</sup>
Prone endurance test [s]	30 ± 26 (3–120)	26 ± 16 (6–71)	0.9942 <sup>a</sup>
Standing maximal strength test [N]	305.3 ± 93.8 (171.6–518.6)	270.2 ± 93.5 (87.2–459.0)	0.1486 <sup>b</sup>
Standing endurance test [s]	86 ± 80 (15–340)	76 ± 62 (2–256)	0.8231 <sup>a</sup>
Modified Biering–Sorensen test value reported to the body weight [s/kg]	4.10 ± 2.17 (1.23–10.85)	4.26 ± 1.52 (1.00–8.08)	0.3231 <sup>a</sup>
Prone maximal strength test value reported to the body weight [N/kg]	5.72 ± 1.98 (2.34–12.02)	5.68 ± 1.93 (1.72–9.85)	0.9311 <sup>b</sup>
Prone endurance test value reported to the body weight [s/kg]	0.61 ± 0.56 (0.06–2.73)	0.54 ± 0.30 (0.18–1.28)	0.6916 <sup>a</sup>
Standing maximal strength test value reported to the body weight [N/kg]	6.23 ± 1.88 (3.27–11.27)	5.83 ± 1.97 (2.31–9.79)	0.4168 <sup>b</sup>
Standing endurance test value reported to the body weight [s/kg]	1.70 ± 1.41 (0.24–6.60)	1.57 ± 1.28 (0.04–5.22)	0.6810 <sup>a</sup>

Note: The average values and standard deviations are given in the table; the minimum and maximum values are given in brackets. a-U–Mann–Whitney; b-t-Student.

The brace is claimed by some medical professionals, parents or patients to negatively impact the back muscles function. No single report concerning the impact of Cheneau rigid brace treatment on the back muscles strength or endurance in IS patients was identified.

Danielsson et al.[9] indicates a significant reduction in back muscle strength in the Sorensen test in patients with IS compared to the control group of healthy people after 20 years after using Boston or Milwaukee brace.

McAviney et al. [8] shows a statistically significant increase in back muscle strength in the Sorensen test in patients with IS treated with Scolibrace and exercise therapy according to a specific SEAS method at 6 weeks and 24-week follow-up.

Bernard[5] indicates a significant reduction in the maximum strength of the back muscles per kilogram of body weight (absolute strength) in a dynamometer test in patients with IS within 1 year of the end of the brace treatment, compared to the group without IS at the same age.

## Conclusion and Significance

The six-month use of Cheneau rigid brace did not affect the strength or endurance of the back muscles in adolescent girls treated for idiopathic scoliosis. Neither the Cobb angle, curve location, nor brace wear time revealed any relationship with back muscle strength or endurance.

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# Follow-up of an Elongation Bending Derotation Brace in the treatment of infantile scoliosis

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**Abstract:** Since 2013, an elongation bending derotation brace (EBDB) has been developed and applied to EOS in our institution. The goals of the study were: 1) to compare radiographic changes before the use of EBDB (Pre-B), in brace (IB), and after the use of EBDB (Post-B) in a minimal two year follow-up; 2) to determine the compliance with the EBDB. Thirteen children diagnosed with an infantile scoliosis (IS) were retrospectively recruited. Under general anesthesia in the OR, child was placed on a Spica casting table, and the spine was manipulated by stockinet straps. Then 3D child's torso was scanned, the EBDB was designed and manufactured for exact fitting to the torso in the corrected position using CAD/CAM technology.<sup>1</sup> Mean age at start of EBDB was 2 years and 6 months. Average follow-up was 36 months. Compliance showed a mean 19 hours per day (14 to 23 hours). Pre-treatment Cobb angle was 40°, in brace 22°, and out of brace 28° ( $p<0.05$ ). Axial vertebral rotation (AVR) by Nash-Moe method improved from 30% before treatment to 21% in brace and 19% at the end of visit ( $p<0.05$ ). Kyphosis was significantly increased from 16° (Pre-B) to 32° (Post-B) ( $P<0.05$ ). However, there was reduction of Rib-vertebral angle difference (RVAD) from 23° (Pre-B) to 11° (Post-B) ( $P>0.05$ ). A cascade of EBDB effectively corrects and stabilizes the 3D spinal deformities in infantile. Thus the EBDB is considered as a successful modality in the treatment of IS children.

**Keywords:** elongation, bending, derotation, infantile

## Introduction

Dating back to 2011, a web-based survey distributed to the members of the Pediatric Orthopaedic Society of North America (POSNA) showed 93% respondents would select nonsurgical management in young child (2-year-old and having 50° of progressive scoliosis), including the use of bracing, casting, halo-gravity traction.[1] Casting and bracing were considered as 55.7%, 32.9% of treatment choices, respectively. In contrast, for a 5-year-old child with a progressive 70° idiopathic scoliosis, only 34.8% physicians preferred a nonoperative approach, having 25.4% casting and 9.4% bracing. Although the Milwaukee brace (MB), thoraco-lumbo-sacral orthosis (TLSO) and other type of braces have been chosen following a serial of castings in the treatment of early-onset of scoliosis (EOS), there were few cohort studies to report efficacy of those braces on the juvenile idiopathic scoliosis (JIS) and rare case studies in infantile scoliosis (IS) (see

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table 1).[2-9] In these early studies on efficacy of bracing management, their success rates ranged from 13% to 78%, with 28% improvement for bracing alone in the recent report.[9]

Since 2013, an elongation bending derotation brace (EBDB) has been developed and applied for the EOS in our institution.[10] However, it was limited to a 12 months visit. The current study reported these IS children who treated by the EBDB in a minimal 24-month follow-up. The goals of the study were: 1) to compare radiographic changes before the use of EBDB (Pre-B), in brace (IB), and after the use of EBDB (Post-B), including Cobb angle in major curve, apical axial vertebral rotations (AVR), Rib-vertebral angle difference (RVAD), and kyphosis; 2) to determine the compliance of the EBDB.

Table 1. Evaluation of bracing treatment in children with JIS or IIS [2-9]

Orthotic Design Protocol	Author	Year	Patients and Outcomes
Milwaukee Brace	Tolo etc.	1978	42 patients with JIS used brace (age 4 to 10) and 13% correction.
Edinburgh brace (Modification of Milwaukee Brace)	Figueiredo etc.	1981	98 patients with JIS (ages 4 to 10) and 44% improvements for Group IIa (mean Cobb-34 °) and IIb (mean Cobb-43°).
Underarm brace	Masso etc.	2002	34 children with JIS (5.9 to 14) and 50% improvements (correction +stabilization).
Charleston Brace (Part-time)	Jarvis etc.	2008	7 boys, 16 girls with JIS or IIS (ages 3 to 10) and 39% correction.
SpineCor Brace	Coillard etc.	2010	150 patients with JIS (age 4 to 10) and overall 43.4% improvements (32.9% correction and 10.5% stabilization)
(RSC TM) Cheneau	Weiss etc.	2012	Case report on 2 year old girl with IIS
Milwaukee, Lyon, or PSAB	Aulisa etc.	2013	113 patients with JIS (ages 4 to 10) and overall 93.7% improvements (77.8% for correction and 15.9 for stabilization)
TLSO (68%), Milwaukee, Charleston	Khoshbin etc.	2014	88 patients with JIS (age 4 to 10) and 28% improvements.

## Methods

Thirteen children diagnosed with an IS were retrospectively recruited, including 9 idiopathic scoliosis and 4 neuromuscular scoliosis. Under general anesthesia in the OR, child was placed on a Spica casting table (see Figure 1A). After longitudinal traction was applied with a bending moment, a translational and de-rotation force was implemented to correct the curve in the coronal and transversal plane by stockinet straps. Meanwhile, 3D child's torso was scanned, then the EBDB was designed and manufactured for exactly fitting to the torso in the corrected position using CAD/CAM technology (see Figure 1B-1D).[10] Based on the Scoliosis Research Society (SRS) criteria of treatment outcomes for AIS,[11] a  $\geq 6^\circ$  change or higher in Cobb angle indicates progression,  $\leq -6^\circ$  change or lower indicates correction, while a range of changes between  $\leq 5^\circ$  or lower and  $\geq 5^\circ$  or higher indicates stabilization. The paired t-test was performed for radiographic comparisons between Pre-B and IB or between Pre-B and Post-B. A liner regression model was use for prediction of relationship among three status. A  $p < 0.05$  was considered significant.

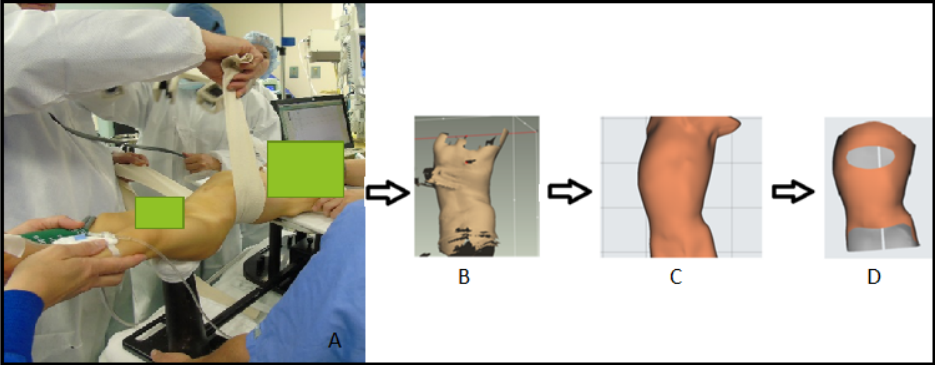


Figure 1. A: A stockinet strap (3"- 4" width) was applied below the apical level to correct the deformed trunk by the physician. This manipulation provided with 3D forces and bending moment, including a medial-lateral translational force, and anterior-posterior derotation force; B: Using a hand-holder scanner registered the 3D surface trunk geometry from the shoulder level to the greater trochanters in a corrected position; C: Using a CAD model, 3D trunk deformity was further corrected per physician's additional requirement if necessary; D: Using a CAD model, a customized brace was created and its digitized file was emailed to CAM for manufacturing a 3D plaster mold as well as beginning in the process of EBDB.

Results and Discussion

The mean age at start of EBDB was 2 years and 6 months (7 to 36 months). Average follow-up was 36 months (24 to 60 months) (Figure 2A-D). Compliance showed a mean 19 hours per day (14 to 23 hours) (Figure 3). Four patients were treated with only serial bracing and the rest had at least one cast (1 to 4). Pre-treatment Cobb angle was 40° (30° to 59°), in brace 22° (6° to 43°), and out of brace 28° (5° to 58°) ( $p<0.05$ ) (see table 2). Axial vertebral rotation by Nash-Moe method improved from 30% before treatment to 21% in brace and 19% at the end of visit ( $p<0.05$ ). Kyphosis was significantly increased from 16° (Pre-B) to 32° (Post-B) ( $P<0.05$ ). However, there was no significant reduction of RVAD from 23° (Pre-B) to 17° (IB) ( $P=0.18$ ) or 11° (Post-B) ( $P=0.053$ ). A liner regression model significantly correlated between Pre-B and IB for Cobb angle ( $P=0.039$ ) (see Figure 4A-B). However, AVR, kyphosis, lordosis, and RVAD did not significantly predict those relationships ( $P>0.05$ ).

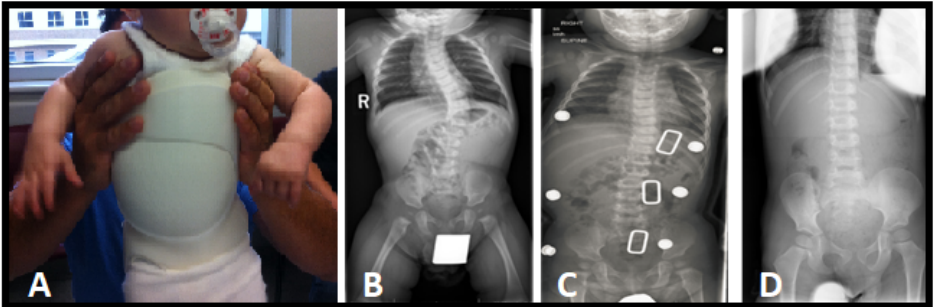


Figure 2. A: 8-month-old boy was diagnosed with infantile idiopathic scoliosis and wore EBDB; B: Before the use of EBDB, his major Cobb angle (T7-L2) was 48°; C: IB Cobb angle was 14°; D: Following 24 months of the use of EBDB, his major curvature was reduced to 5°.

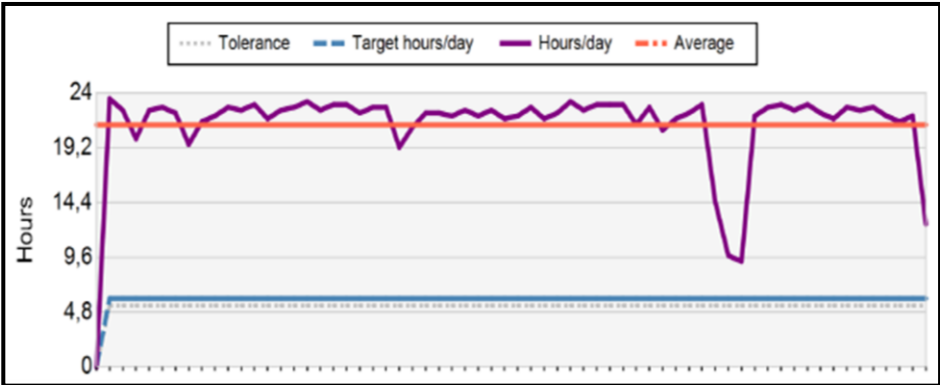


Figure 3. The heat sensor embedded in the brace recorded the actual hours of wearing the brace daily until downloading the data in three months (including the real hours, averaged hours, or pre-set target hours per day if needed)

Table 2. Comparisons of radiographic parameters among before brace, in brace, and after brace (mean  $\pm$  SD, paired t-test, p value)

X-ray measurements	Before brace (Pre-B)	In brace (IB)	Out of brace (Post-B)	P value
Cobb angle (°)	40	22	28	<0.001 0.01
Nash-Moe (in %)	30%	21%	19%	0.037 0.011
Kyphosis (°)	16		32	0.002
RVAD (°)	23	17	11	0.18 0.053

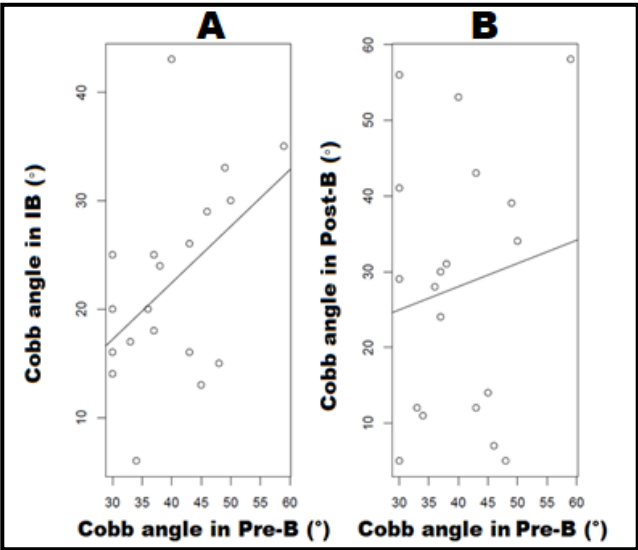


Figure 4. A: A liner regression model with a higher slope between Pre-B and IB, indicative of a larger Cobb angle with less than 50° resulting in a significant in-brace correction ( $P=0.039$ ); B: A liner regression model with a lower slope predicted a reduction of Cobb angle at the end of follow-up but no statistically significant relationship ( $P=0.55$ ).

## Conclusion and Significance

A cascade of EBDB braces effectively corrects or stabilizes the 3D spinal deformities in infantile. It can monitor compliance. There are reduced numbers of castings and general anesthetics with bracing. It is cost efficient, and there is improved quality of life. Thus the EBDB can be considered as a successful modality in the treatment of IS children.

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# Boston vs. Providence brace in treatment of Adolescent Idiopathic Scoliosis

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**Abstract:** Adolescent idiopathic scoliosis (AIS) is a complex condition characterized by a lateral curvature and axial rotational deformity of the spine. Though bracing is effective, a need remains to identify the effect brace type has on spine curvature. To examine differences in patient demographics between the Boston and Providence brace, determine the corrective change in Cobb angle and RVAD and investigate the effect of brace type on curvature over time. A retrospective chart review was conducted of 105 patients diagnosed with AIS from 2013-2016 at CHW. Five spinal parameters were measured: Cobb angle, Risser, RVAD, kyphosis and lordosis. Data was collected before bracing, in-brace and at 24 months. A final treatment outcome of either Cobb angle correction (reduction  $>5^\circ$ ), stabilization (change  $\pm 5^\circ$ ) or progression (deterioration  $>5^\circ$ ) was then evaluated. Providence brace provided significantly greater in-brace thoracolumbar Cobb angle and RVAD reduction in comparison to the Boston brace (Cobb angle  $-21.9^\circ$  vs.  $-12.5^\circ$ ; RVAD:  $-1.8^\circ$  vs.  $1.62^\circ$ ). Similarly, Providence users had a significantly smaller increase in Cobb angle and RVAD over time (Cobb angle: thoracic  $14.2^\circ$  vs.  $15.0^\circ$ ; thoracolumbar  $23.6^\circ$  vs.  $26.0^\circ$ ; RVAD:  $5.2^\circ$  vs.  $8.5^\circ$ ). Ultimately, no significant difference in final treatment outcome was established between brace groups. Although the Providence brace provides less of an increase in thoracic and thoracolumbar curvatures over time, both braces are an effective treatment and achieve comparable outcomes. Selection of braces may vary with primary curve angle, curve location, patient compliance and quality of life.

**Keywords:** AIS, Boston brace, Providence brace, RVAD

## Introduction

Adolescent idiopathic scoliosis (AIS) is a complex 3-dimensional condition that is characterized by both a lateral curvature and axial rotational deformity of the spine. In order to slow curve progression various forms of rigid bracing, such as the Boston and Providence Brace, have been used as a form of nonoperative conservative treatment.[4] The goals of conservative treatment for AIS include slowing curve progression, improving the respiratory function, reducing pain or discomfort and improving the quality of life.

Previously the effectiveness of wearing a brace has been controversial with past studies showing inconclusive results. However, a study by Weinstein *et. al* demonstrated that bracing is an effective form of treatment and does in fact slow the progression of curvature in AIS patients. The rate of treatment success for patients randomly assigned

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to bracing was 75% in comparison to patients assigned to observation which was found to be only 42% successful.[4]

Despite the known benefits and effectiveness of bracing for AIS, there remains a need to identify the effect different brace types have on spine curvature over time. The Scoliosis Research Society (SRS) has established a set of criteria with the goal to improve research and create a standardized AIS treatment protocol.[3] The SRS recommends determining the effectiveness of a brace by calculating the final treatment outcome: correction (Cobb angle reduction by  $>5^\circ$ ), stabilization (Cobb angle change of  $\pm 5^\circ$ ) or progression (Cobb angle deterioration by  $>5^\circ$ ).[6] Research studies on AIS have begun to implement these recommendations, however additional studies are needed in order to establish a standardized bracing treatment protocol.

Numerous brace types have been created over the years to treat AIS since the first removable cervicothoracolumbosacral orthosis (CTLSO), the Milwaukee Brace, was first introduced in 1946.[3] Two brace types that are widely used clinically today are the Boston and Providence Brace. The Boston Brace, which is the most frequently used scoliosis TLSO in North America, is a brace that is typically worn for 22 hours per day.[1] In contrast, the Providence Brace is typically only worn at night while sleeping for approximately 8 hours per day.[1]

A prior study by Janicki *et al* compared the effectiveness of the Boston and Providence braces in the treatment of AIS. The results were found to not be statistically significant but showed that the Providence brace was more effective for avoiding surgery and preventing curve progression for initial curves with Cobb angles between  $25\text{--}40^\circ$ . In contrast to prior studies the brace success rate was much lower than has been previously described with both brace types with 79% of Boston and 60% of Providence users requiring surgical correction.[1] Due to these findings further research is needed to determine the effectiveness of these two brace types.

An additional need exists to identify factors other than Cobb angle that can help predict curve behavior and response to brace treatment. One such factor is the Rib Vertebral Angle Difference (RVAD) which has historically been used in infantile scoliosis but only recently considered a potentially beneficial measurement for AIS. Xu Sun *et al* did examine the change in RVAD in AIS patients treated with the Milwaukee Brace, but no studies have examined the change in RVAD for AIS patients treated with either the Boston or Providence Brace.[5]

The aims of this study were to examine differences in patient demographics and radiographic measurements between the Boston brace and Providence brace, determine the corrective change in Cobb angle and RVAD provided by each brace and investigate the effect of brace type on curvature over time. We believe the Boston and Providence brace will provide comparable in-brace curve correction but the Boston brace will result in greater reduction of spinal malalignment in the coronal plane as a function of time.

## Methods

A retrospective chart review was conducted of a total of 105 patients, between the ages of 10-18, diagnosed with AIS from October of 2013 to May of 2016 at Children's Hospital of Wisconsin. Patients were prescribed either a Boston (n=70) or Providence brace (n=35) as treatment with radiographs taken both in and out of the brace for at least two years or until skeletal maturity. Patients with prior brace treatment, history of spinal surgery or any neuromuscular disorder were excluded from this study in order to

eliminate any possible confounding variables. Five spinal parameters were measured: Cobb angle, Risser grade, RVAD, kyphosis and lordosis. Data was collected before bracing, in-brace and at twenty-four months.

Descriptive statistics were used to determine baseline patient characteristics. The degree of in-brace reduction of Cobb angle and RVAD were compared between the two groups using a student *t*-test analysis. The change in curvature from the start to end of bracing was then determined using an ANCOVA analysis. The Brace type switch rate was investigated using an Odds ratio. A final treatment outcome of either correction (Cobb angle reduction  $>5^\circ$ ), stabilization (Cobb angle change  $\pm 5^\circ$ ) or progression (Cobb angle deterioration by  $>5^\circ$ ) was evaluated between the two groups via a Fisher's exact test analysis. A *p*-value  $<0.05$  was considered statistically significant.

## Results and Discussion

No significant differences were found between the two brace groups with regards to gender, age at diagnosis, initial Risser grade, length of brace treatment or number of patients requiring a posterior spinal fusion. Boston users were found to have larger thoracic, thoracolumbar and lumbar Cobb angles than the Providence group at the onset of bracing (Thoracic Cobb angle: Boston  $28.4^\circ$  vs. Providence  $22.8^\circ$  ( $p=0.005$ ); thoracolumbar Cobb angle: Boston  $28.4^\circ$  vs. Providence  $24.8^\circ$  ( $p=0.003$ ) (Figure 1); lumbar Cobb angle: Boston  $24.5^\circ$  vs. Providence  $17.3^\circ$  ( $p=0.02$ )). Additionally, Boston users reported a statistically greater patient reported hours of brace wear per day (15.8 hrs./day) in contrast to Providence users (7.2 hrs./day) ( $p<0.0001$ ). Those that were initially treated with a Providence brace were also found to be 6.9 times more likely to switch brace types compared to patients that started with a Boston brace over the course of their treatment with bracing.

The Providence brace was found to provide significantly greater in-brace thoracolumbar Cobb angle (Figure 1) and RVAD reduction in comparison to the Boston brace (Cobb angle  $-21.9^\circ$  vs.  $-12.5^\circ$  ( $p<0.001$ ); RVAD:  $-1.8^\circ$  vs.  $1.62^\circ$  ( $p=0.04$ )). The Providence brace did show a greater reduction of in-brace thoracic and lumbar curve Cobb angles in comparison to the Boston brace, however this difference was not found to be statistically significant (Thoracic Cobb angle:  $-14.8^\circ$  vs.  $-11.4^\circ$  ( $p=0.12$ ); Lumbar Cobb angle:  $-10.5^\circ$  vs.  $-5.5^\circ$  ( $p=0.27$ )).

Similarly, in comparing the curvatures over time from the onset of bracing to after 24 months of treatment, Providence users were found to have significantly less of an increase in Thoracic and Thoracolumbar curve Cobb angles and RVAD than Boston users (Thoracic Cobb Angle:  $14.2^\circ$  vs.  $15.0^\circ$  ( $p=0.0006$ ); Thoracolumbar Cobb angle:  $23.6^\circ$  vs.  $26.0^\circ$  ( $p<0.0001$ ) (Figure 1); RVAD:  $5.2^\circ$  vs.  $8.5^\circ$  ( $p<0.001$ ). No significant difference was found in the Lumbar curve Cobb angle between Providence and Boston users (Lumbar Cobb angle:  $-4.2^\circ$  vs.  $-1.5^\circ$  ( $p=0.95$ )).

The Providence brace notably provided significantly greater in-brace curve correction in comparison to the Boston brace for all 3 curve types, though only the in-brace thoracolumbar curve Cobb angle correction was statistically significant. This finding is likely due to the over corrective nature of the Providence brace and was probably a major contributor to the reduction of the RVAD as well.

While Providence users achieved significant in-brace reduction and smaller increases in curvatures over time, they also reported significantly fewer hours of brace wear per day compared to Boston patients (7.2 vs. 15.8 hours/day). However, this finding

reflects the recommended length of brace wear per day for each type and is limited by the brace wear compliance being self-reported by the patients in this study.

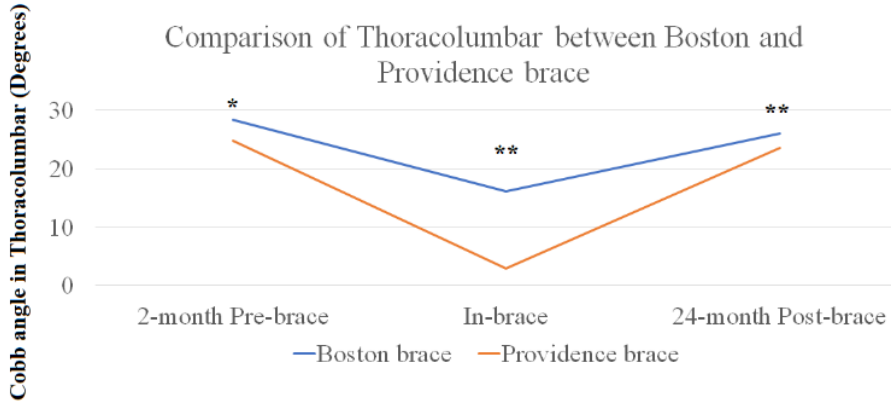


Figure 1. Significantly reduced Cobb angle in thoracolumbar segment in Providence brace than that in Boston brace, especially in-brace (\*  $P=0.003$ ; \*\*  $P<0.001$ )

The brace type switch rate is likely due to the difference in brace design. The Providence brace is designed to over-correct and has an asymmetric design that would be difficult to wear when not sleeping. If Providence brace patients' curves progressed it would be challenging to increase the length of brace wear per day. Whereas the Boston brace is constructed to be worn for ~22 hours per day and would easily be able to be worn for fewer hours if a patient's curve progression began to plateau. This disparity is likely the reason between the switch rate observed within this study.

Though the Providence brace was found to provide significant reduction of in-brace curvatures and less progression over time in comparison to the Boston brace, there was ultimately no significant difference in final treatment outcomes between the two groups despite the baseline curvatures being significantly higher in Boston users.

**Conclusion and Significance**

Although the Providence brace provides less of an increase in thoracic and thoracolumbar curvatures over two years, both braces are an effective treatment for AIS and achieve comparable outcomes. The nighttime Providence brace is a practicable alternative to the full-time Boston brace. Selection of braces may therefore vary with regards to a primary curve angle, curve location, patient compliance and quality of life.

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# Bracing for infantile scoliosis: no sedation needed

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**Abstract:** Mehta casting technique applied under anesthesia is standard treatment for infantile scoliosis (IIS). However, concern has been raised about frequent anesthesia in children less than three years. The development of a customized thoracolumbar sacral orthosis (TLSO) could avoid the risks of Mehta casting. To develop a bracing technique for IIS that achieves patient compliance and scoliosis correction. Nine patients with IIS were offered a custom TLSO as an alternative to Mehta casting. One patient declined due to an insurance issue. No anesthesia was required for measurement or fitting of the TLSO. A temperature sensitive monitor recorded wear time. Brace success was determined by radiographic correction and adherence to prescription of greater than 18 hours per day. Eight patients had brace treatment with mean(range): age 19(12-44) months, curve magnitude 34° (22-44°), rib vertebral angle of greater than 20° with follow-up 17(3-28) months. In brace correction was less than 15 degrees in 6 of 8 patients. Compliance monitor recorded wear: 4 patients ≥ 18 hours, 2 patients 16-18 hours, 1 had 14 hours, and 1 monitor malfunctioned and could not be read. Brace design evolved to maximize ipsilateral abdominal relief away from the lateral apical shift of the design. Foam lining was added to prevent skin irritation through the relief opening. Average number of braces per year =2.2. A customized TLSO can achieve in brace correction comparable to Mehta casting with acceptable compliance and without the need for general anesthesia, while allowing bathing and skin care.

**Keywords:** Spine, Scoliosis, Brace

## Introduction

The standard of care for infantile scoliosis has been Mehta casting placed under general anesthesia or sedation. Mehta described an elongation derotation flexion casting technique in 136 patients under age 4 with reversal of scoliosis being associated with younger age at diagnosis and less severe curvature.[1] The Mehta technique involved serial casts changes under anesthesia with the frequency of cast change being determined by the age of the infant. The success of the Mehta casting has been attributed to the expert casting technique, with gradual correction achieved with the frequent cast reapplication and the consistency of wear providing 24 hours per day in the cast.

The effect of general anesthesia in young children on brain development has become a concern.[2] In 2016, the FDA issued a warning in the form of a drug safety communication that repeated use of general anesthetic in child < 3 years of age “may affect the development of child’s brain.”[3] The Mehta technique may involve greater than 10 casts placed under general anesthesia in the infant one or two years of age. The

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conflict between serial casting to correct infantile scoliosis weighed against potential brain injury with repetitive casting has led to the search for alternative methods to treat infantile scoliosis.

Effective full-time bracing is an attractive alternative to achieve success without risk and cost associated with repetitive general anesthetic administration. Previous attempts at bracing infantile scoliosis may have failed due to inadequate brace wear time, orthosis design, or treatment strategy. We present a case series of successful brace treatment for infantile scoliosis following the same principles of Mehta casting of gradual correction and sustained daily brace wear time. Evolution of the brace design occurred based on patient experience with close monitoring of wear time.

## Methods

A consecutive series of 9 patients with infantile idiopathic scoliosis were offered treatment with a custom fabricated TLSO as an alternative to repetitive Mehta casting. Indications for bracing treatment were scoliotic curve magnitude greater than 20 degrees with rib vertebral angle difference of greater than 20 degrees. All patients had a negative MRI scan of the spinal column. Parents were counselled that Mehta casting was the standard of care but would require multiple changes under anesthesia. Parents were instructed that brace wear time should be maximized to mimic EDF casting with allowance of brace removal for bathing and episodes of respiratory or gastrointestinal distress. One patient declined due to an insurance issue. No anesthesia was required for measurement or fitting of the TLSO which was accomplished with parental assistance. Body measurements were obtained by casting or surface scanning in a corrected position by the orthotist. Computer design modeling of the scanned torso was applied to generate a lateral shift at the apex of the curve with ipsilateral void following three dimensional principles. A temperature sensitive monitor was placed to record wear time and results were shared with the parents at each visit. Radiographs of the spine were obtained prior to brace application, after initial brace application, and then periodically during treatment period. Brace success was determined by radiographic in brace correction and adherence to brace wear prescription of greater than 18 hours per day.

## Results and Discussion

The mean age of the 8 patients was 19 months (range 12-44 months). Two patients early in the series had initial Mehta casting then transitioned to exclusive brace treatment. Both patients had correction to less than 15 degrees in the initial cast prior to introduction of the bracing alternative to repetitive casting. Pre-treatment curve mean magnitude was 34° (range 22-44°) with rib vertebral angle of greater than 20° in all patients. Follow-up mean 17 months (range 3-28 months) In brace correction was to less than 15 degrees in 6 of 8 patients. Compliance monitor recorded 18 hours or greater in 4 patients, 2 patients achieved 16-18 hours, 1 had 14 hour and 1 monitor malfunctioned and could not be read. All patients remain under active treatment. No patient was intolerant of bracing and no parents requested to discontinue bracing treatment. Brace design has evolved in response to patient/parent feedback. Posterior opening was used in order to maximize relief area of the abdomen. Insufficient abdominal relief was recognized in the youngest patient, age 12 months, by decreased feeding and weight loss, which resolved with brace

modification. A foam liner was added to prevent skin and rib irritation through the relief opening in some patients. A lateral shift away from the apex in thoracolumbar region with ipsilateral relief was built into the replacement brace design. Brace replacement was based on growth with mean number of braces per year of 2.2.

## Conclusion and Significance

A customized TLSO can achieve in brace correction comparable to Mehta casting with acceptable compliance without the need for general anesthesia while allowing bathing and skin care. Parent satisfaction has been high in this initial series. Further follow up will be necessary to determine the persistence of in brace correction, durability of correction, and optimal brace wear duration.

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# Development of orthosis following EDF serial casting for infantile scoliosis

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**Abstract:** Elongation-de-rotation-flexion (EDF) casting is a popular treatment for early-onset-scoliosis (EOS). However, casting every 2 to 3 months using general anesthesia may affect cognitive function.[1,2] Aims of this study: 1) to develop a new orthosis for EOS treatment based on EDF technique (EDFO) and traction frame; 2) to evaluate emerging radiographic results from treatment. Mehta's EDF serial casting method and AMIL traction frame were used to manually correct the spine for 3D trunk scan. Afterward, a digital spinal model was created and helped design the EDFO with CAD/CAM technology. Radiographic measurements included Cobb angle, RVAD, and thoracic height and width. Six patients (2 girls; 4 boys) diagnosed with idiopathic EOS were enrolled in the study. EDFO was applied at mean 36.5 months of age, after final EDF casting. The average major Cobb angle stabilized after treatment. Average RVAD increased. The average normalized thoracic width at last EDFO out-of-brace was less than prior to EDFO. The new asymmetric EDFO offers an alternative to serial casting and TLSO. EDFO is considered a cost-effective, safer, more breathable, removable, and less invasive modality.

**Keywords:** Elongation, derotation, flexion, infantile scoliosis, orthosis

## Introduction

Early-onset-scoliosis (EOS) affects individuals up to the age of 10 years. Etiologies for EOS include neuromuscular, syndromic, congenital, and idiopathic. Neuromuscular causes include cerebral palsy, spinal muscular atrophy, brain or spinal cord injury, and spina bifida. Syndromic causes include Ehlers-Danlos, Marfan syndrome, Prader-Willi, and neurofibromatosis. A congenital etiology of EOS entails in utero malformations. EOS presents at a time of rapid growth in vertical height as well as the rib cage in children. Therefore, the impact upon spinal development may affect proper cardiopulmonary advancement.[3-5] Death in patients with scoliosis is greater in younger populations compared to adolescent populations.[6]

Treatment options for EOS include observation, casting, bracing, and surgery. Patients with curves having a Cobb angle greater than 30-35 degrees are likely to progress. Conservative management is preferred at this stage. Elongation-derotation-flexion (EDF) serial casting is one of the main conservative treatment options for EOS patients.[7] Mehta's EDF serial casting method corrects by elongation of the spine by stretching at the pelvis and head, derotation of the rib prominence by an oblique and

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perpendicular force, and flexion by a lateral force.[2,8] Mehta and others have found optimal curvature results when EDF serial casting was started early in EOS patients. While correction and stabilization were likely for younger patients, for older EOS patients, EDF serial casting either stabilized the curvature or delayed the need for surgery.[1,9-14]

Although EDF serial casting is popular, each cast application occurs under general anesthesia every 2-3 months. This frequent use of general anesthesia may lead to cognitive impairment.[1] Because of this concern, alternative EOS treatment options have been offered, such as the thoracolumbosacral orthosis (TLSO).[15] However, aside from challenges in making braces for young patients, the pressure caused from wearing TLSO may decrease compliance and result in irritation.[16,17] In this study, we combined the technique from EDF serial casting with brace construction to present yet another orthotic solution for EOS, termed EDFO. This combination would reduce the need for frequent applications of general anesthesia as well as reduce the pressure caused by symmetric TLSO. This study seeks to develop a new orthosis based on the EDF technique and traction frame for EOS treatment and to evaluate emerging radiographic results from treatment.

## Methods

This is an IRB-approved retrospective case series which includes six patients (2 female) who were diagnosed with idiopathic EOS. After the final EDF serial cast was applied, EDFO treatment was started. Patients were included in this study based on the following criteria: 1) under the age of 10 years; 2) EOS diagnosis; 3) no other past spinal surgeries; 4) EDFO treatment started after a final EDF serial cast.

Mehta's EDF technique entails elongation by longitudinal traction of the spine by stretching at the pelvis and head, de-rotation of the rib prominence by an oblique and perpendicular force at the ribs, and flexion by a lateral force.[2] At the final EDF cast, a scan of the patient's 3D trunk using the hand-holder scanner (Polhemus Fastscan Scorpion, Colchester, VT) was completed while manually held in the corrected position. Afterward, a digital model using computer aided design (CAD) (Rodin SAS, Pessac, France) was made based on the scan. After computer aided manufacturing, the new orthosis was fitted and adjusted for the patient by an orthotist.

Anteroposterior radiographs were obtained prior to EDFO treatment, out-of-cast (Pre-OOC); after EDFO initiation, in-brace (Post-IB); during treatment but out-of-brace (Post-OOB), and at final EDFO treatment, out-of-brace (Last-OOB). Measurements were extracted using digital measuring tools in PACS on Epic include Cobb angle, RVAD, and thoracic height and width.[18,19] A digital ruler was used to measure thoracic height from the upper endplate of T1 to the lower endplate of T12, as well as thoracic width at T3, T6, and at the widest thoracic point. The width was normalized by the width/height ratio.[20]

The Scoliosis Research Society (SRS) criteria for spine correction in adolescent idiopathic scoliosis were used to analyze the Cobb angles of EOS patients in this study. Correction is a Cobb angle reduction of  $>5^\circ$ , stabilization is a change between  $-5^\circ$  to  $5^\circ$ , and progression is a deterioration of  $>5^\circ$ .[21] The standard error of the mean (SEM) was calculated for each parameter. Cobb angle, RVAD, and thoracic height progression for each patient was shown using simple linear regression.

Results and Discussion

Six patients (2 girls; 4 boys), diagnosed with idiopathic EOS were enrolled in the study. Following final EDF casting, EDFO was applied at a mean age of 36.5 months (11.5-58.5). Mean follow-up at last EDFO out-of-brace (OOB) scan was 16.3 months (5.5-30.5). Major Cobb angle prior to EDFO started at an average of 45° (±7), then reduced to 31° (±7) in-brace, and ended at 45° (±13) at the last EDFO OOB (see table 1 and figure 1). RVAD prior to EDFO, in-brace, and at the last EDFO OOB were 26° (±13), 33° (±11), and 37° (±11) (see figure 1). Mean normalized thoracic width at last EDFO OOB was less than prior to EDFO: width at T3 (prior: 0.77, in-brace: 0.83, last OOB: 0.77), at T6 (1.01, 1.00, 0.99), and at its widest (1.18, 1.09, 1.08). Thoracic height increased from prior EDFO at 14.4 cm (±0.6) to last EDFO OOB at 15.7 cm (±1). Three out of six curves were corrected, one stabilized, and two progressed, resulting in a 67% success rate.

Table 1. Changes in Cobb angle, RVAD and width ratio before, in, and after bracing (Mean ± SE, ratio)

Parameters	Pre-OOC	Post-IB	Last-OOB
	Mean ± SE	Mean ± SE	Mean ± SE
Cobb angle (°)	45 ± 7	31 ± 7	45 ± 13
RVAD (°)	26 ± 13	33 ± 11	37 ± 10
Width ratio (T3)	0.77 ± 0.04	0.83 ± 0.04	0.77 ± 0.05
Width ratio (T6)	1.01 ± 0.05	1.00 ± 0.04	0.99 ± 0.06
Width ratio (Widest)	1.18 ± 0.07	1.09 ± 0.06	1.08 ± 0.08

Note: OOC denotes out-of-cast; IB denotes in-brace; OOB denotes out-of-brace; RVAD denotes rib vertebral angle difference.

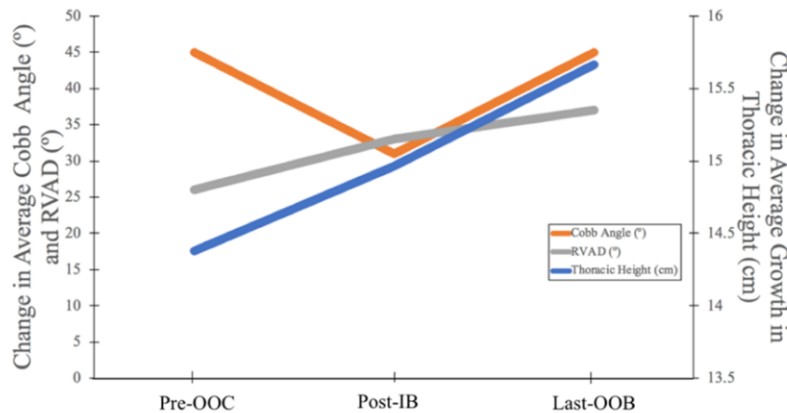


Figure 1. Progression of average thoracic height, RVAD, and Cobb angle before EDFO, in-brace, and after EDFO (Pre-OOC: measurement made out-of-cast; Post-IB: in-brace; Last-OOB: final measurement out-of-brace).

The EDFO treatment had a 67% success rate with correction of half the major Cobb angles and stabilization of one. The major Cobb angle had an average in-brace correction of 31.4%; RVAD had a change of -7.2 degrees. The study’s results bolster EDFO treatment when considering Mehta’s prediction for scoliosis progression. Namely,

scoliosis progresses when the RVAD is 20 degrees prior to treatment and corrects when the RVAD is less than 20 degrees prior to treatment.[19]

EDF serial casting has been shown to stabilize or reduce the curvature in EOS patients.[8] But aside from treatment, the EDF serial casting technique is also used to delay the need for surgery in growing patients with EOS.[22] A “cast holiday” of four or more weeks within the first 18 months of EDF serial casting was suggested by one study to result in fewer successful outcomes. The study showed patients with idiopathic EOS reaching scoliosis <15 degrees with an odds ratio of 4.4 in favor of no cast holiday.[23] The study, which also used EDF TLSO during the cast holiday instead of custom CAD/CAM-designed braces, suggests brace treatment is not as effective as casting. However, this study did not describe in detail the methods used to make the EDF TLSO nor the duration of use during the holiday, meaning brace design, development, and use was not as particular as in our study.

Casting presents several challenges including frequent cast changing, frequent applications of general anesthesia, increased cost due to numerous casts, and temporary pulmonary restriction during cast setting.[24,25] EDFO treatment resolves many of these concerns because it reduces the number of necessary casting episodes. No research currently establishes CAD/CAM-designed EDFO as an orthotic alternative to EDF serial casting. Although all children in this preliminary study had serial EDF casting followed by an EDFO using the AMIL table at the final cast, we would like to introduce this technique for children with EOS who may not have or need prior serial casting.

## Conclusion and Significance

This study uses the AMIL traction frame and EDF technique by Mehta to create a first-of-its-kind asymmetric custom-fitted EDFO. This orthosis is a cost-effective, safer, more breathable, removable, and less invasive modality when compared to traditional EDF serial casting.

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# Chapter 9

## Physiotherapeutic Scoliosis-Specific Exercises

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# Feasibility and effects of 6 -month home-based digitally supported E-Fit program utilizing high-intensity interval exercises in girls with adolescent idiopathic scoliosis: a randomized controlled pilot study

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**Abstract:** Adolescent idiopathic scoliosis (AIS) patients have lower physical activities when compared with healthy controls, and are associated with lower bone mineral density (BMD), muscle strength and poorer quality of life (QoL). We aimed to assess the feasibility and effects of 6-month home-based digitally supported E-Fit comprised of high-intensity interval exercises for AIS patients. 40 AIS girls aged 11-14 were randomly assigned to E-Fit or control group. E-Fit group participated in an online 6-month home-based exercise program. At baseline, 6-months and 12-months follow-up, BMD using dual-energy X-ray absorptiometry, muscle functions, physical activity using Modified Baecke Questionnaire (MBQ), and QoL using Scoliosis Research Society-22 (SRS-22r) and feedback questionnaire were investigated. 14 in E-Fit and 16 in control group completed the study. Both groups had similar baseline characteristics. At 6-months, E-Fit group showed better improvement and significant interaction effect in left femoral neck bone mineral content ( $p=0.021$ ) and isometric curl up test ( $p=0.04$ ). Left arm lean mass showed better improvement between 6-months and 12-months follow-up ( $p=0.046$ ) and whole-body areal BMD had significant interaction effect at 12-months follow-up ( $p=0.077$ ). Improvement on self-image, work and sports participation were noted in E-Fit group across time. 70% of E-Fit participants were positive towards domestic application via online platform. E-Fit showed some benefits on bone health, muscle functions, physical activity and QoL measures. Current study indicated some potential physical and psychological benefits of E-Fit for AIS girls. E-Fit was feasible to conduct online at home and might have value of promoting exercise habits among relatively inactive AIS girls.

**Keywords:** Home-based exercise program, bone health, muscle functions, quality of life

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## Introduction

Adolescent idiopathic scoliosis (AIS) patients have lower physical activities when compared with healthy controls, and are associated with lower bone mineral density (BMD), lower skeletal muscle mass and decreased in muscle strength and poorer quality of life (QoL).[1-3] Untreated or improperly treated AIS patients may result in significant sequelae such as curve progression leading to functional disabilities and morbidities extended into adulthood. Regular exercises during adolescences have metabolic, physiological, neuromuscular and psychosocial benefits which these gains seem to extend into adulthood. We hypothesized that a 6-months home-based E-Fit exercise intervention (E-Fit) utilizing short duration and high-impact weight bearing exercises might improve bone health, muscle functions and QoL in AIS girls. We aimed to assess the feasibility and effects of 6-month home-based digitally supported E-Fit comprised of high-intensity interval exercises for AIS patients.

## Methods

Subjects aged between 11-14 were recruited if they had diagnosis of AIS confirmed by clinical and standard standing long x-ray examinations, Cobb angle  $\geq 15^\circ$ , newly diagnosed at the Scoliosis Clinic, The Chinese University of Hong Kong, Hong Kong SARR, China, without prior treatment and cleared for physical activity by doctor. Exclusion criteria were Cobb angle  $\geq 40^\circ$ , scoliosis with any known etiology such as congenital scoliosis, neuromuscular scoliosis, scoliosis of metabolic etiology, scoliosis with skeletal dysplasia, known endocrine and connective tissue abnormalities, known heart condition or other diseases that could affect the safety of exercise, eating disorders or gastrointestinal malabsorption disorders and currently taking medication that affects bone or muscle metabolism.

Forty AIS girls were recruited and randomly assigned to E-Fit (n=20) or control group (n=20). E-Fit group participated in a 6-month home-based exercise program (E-Fit) with demonstration videos administered using an online platform. The E-Fit was specifically designed to be performed in small home environment and was characterized by a broad range of high-impact weight bearing exercises for the whole body, applying at varying speed and directions to adequately load the musculoskeletal system. The E-Fit group performed exercise intervention 5 days a week with 2-days rest interval for 6 months. The control group had no intervention and received only standard care. Outcomes measures were obtained at baseline, 6-months and 12-months follow-up including 1) BMD using dual-energy X-ray absorptiometry, 2) muscle strength and endurance tests of trunk, upper and lower limbs, 3) physical activity level using Modified Baecke Questionnaire (MBQ), and 4) QoL measures using Scoliosis Research Society-22 (SRS-22r) and feedback questionnaire were investigated.

## Results and Discussion

A total of 30 subjects (14 in E-Fit and 16 in control group) completed the study. The recruitment (71.4%) and loss to follow-up (25%) rates were satisfactory. Both groups had similar baseline characteristics. The E-Fit was well received by AIS girls as they

could follow the exercise instructions and perform the exercises at home easily. No adverse event was reported by the subjects in this study. The results could support the assertion that short bouts of high-impact weight bearing exercises are safe for AIS girls. To our knowledge, this is the first clinical trial completed to investigate the effects of high-impact weight bearing with AIS girls.

Our preliminary findings showed some beneficial effects of E-Fit on bone health, muscle functions, physical activity and QoL measures. At 6-months, E-Fit group showed better improvement and significant interaction effect in left femoral neck bone mineral content ( $p=0.021$ ) and isometric curl up test ( $p=0.04$ ). Left arm lean mass showed better improvement between 6-months and 12-months follow-up ( $p=0.046$ ) and whole-body areal BMD had significant interaction effect at 12-months follow-up ( $p=0.077$ ). These changes were also observed in other diseased population, healthy adults and adolescence performing high-impact weight training exercises and might indicate a potential benefits of muscle functions and performance to exercise in early life.[4]

Improvement on self-image, work and sports participation were noted in E-Fit group across time. 70% of E-Fit participants were positive towards domestic application via online platform. Previous studies also reported similar findings that AIS patients have lower physical activity level[4] and lower quality of life.[3] E-Fit could potentially induce positive psychological impacts such as improving self-image and promoting habitual physical activity among relatively inactive AIS girls. E-Fit might also help to generate better self-image, relieve stress and encourage healthy lifestyle for preventing potential psychological and physical issues in later life.

Several limitations of this pilot study should also be noted. The compliance of accelerometer was low which posed challenges to monitor exercise compliance and intensity to assess the optimal treatment effects. Strategies with more robust monitoring of exercise compliance should be employed so that a more accurate record of compliance data could be obtained. Since this was a pilot study with relatively small sample size, the statistical power might be low that the effects of certain outcome measures could not be reflected. Lastly, the actual exercise intensity of our subjects was unable to quantify in this pilot study. Laboratory exercise testing can be used in future studies to determine the physiological responses and optimal intensity of E-Fit.

## Conclusion and Significance

Current study indicated some potential physical and psychological benefits of E-Fit for AIS girls. E-Fit was feasible to conduct online at home and might have the value of promoting exercise habits among relatively inactive AIS girls.

## Acknowledgment

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# Adult patient perceptions on the effectiveness of scoliosis specific exercises

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**Abstract:** There is a paucity of research focusing on adults with scoliosis, yet many of these individuals suffer from pain and disability. Recent literature has demonstrated that for this patient population general physical therapy is no better than other non-operative treatment options.[1-3] This study assessed the perceptions of the effectiveness of Physiotherapeutic Scoliosis Specific Exercises (PSSE) on adult scoliosis. The purpose of this study is to present the results of a retrospective analysis of how adults with scoliosis perceive that physical therapy utilizing PSSE has impacted their quality of life (QoL), function, and pain. A 10 question survey was sent via a secure server (Qualtrics) to all PSSE participating patients  $\geq 18$  years old from one PSSE specialty clinic from the beginning of the PSSE program, 7 years. Survey responses were anonymous, collected by someone other than the primary investigator, and statistics were calculated with SPSS 24 (IBM Corp., Armonk, NY). Results: Fifty-seven adults (88.9% female) responded to the survey (55% response rate) with 67.2% being over the age of 55 years. The majority (61.9%) felt that PT had moderately or significantly positively impacted their QoL. The most common number of PT visits ranged from 5 – 10, after which 71.9% of participants were either somewhat or very confident in their ability to perform their PSSE program unsupervised at home. The most common frequency of home exercise program (HEP) performance was 1-2 times per week (46.0%) for a duration of 5 – 40 minutes. Quantitative analysis of exercise adherence using a Spearman's rho ( $r_s$ ) revealed positive associations between confidence in correctly performing the HEP with the perceived positive impact of the exercises ( $r_s = .45$ ,  $p < .001$ ), the greater frequency of performing the HEP ( $r_s = .30$ ,  $p = .024$ ) and greater time performing the HEP ( $r_s = .33$ ,  $p = .004$ ). This retrospective analysis showed that 61.9% of adults with scoliosis felt that PT utilizing PSSE had moderately or significantly positively impacted their QoL. Adherence to a HEP is critical to the success of the program. Greater confidence in correctly performing the HEP was positively correlated with perceived impact, frequency and time spent exercising. The sample was limited to adults from one clinic that specializes in scoliosis and may not be generalizable to other clinics.

**Keywords:** Physiotherapeutic Scoliosis Specific Exercises (PSSE), Adult Scoliosis, Quality of Life, and Non-surgical Scoliosis Management.

## Introduction

The most recent research on the impact of physical therapy (PT) on adults with scoliosis has been grim. Two studies looked at conservative treatment outcomes for patients with adult scoliosis and degenerative scoliosis. The main conclusions were that there is low quality evidence for any non-operative treatment options for adult degenerative scoliosis.[2,3] Similarly, Bridwell et al. found that in adults with scoliosis

“operative patients out-performed non-operative patients by all measures”. [1] Based on these studies we must ask ourselves, as a profession, if we should be treating this population. Adult patients with scoliosis are usually seeking treatment for pain resolution. Physical therapists are trained to treat low back pain and have successful outcomes with research to support our continued care of this population. [4] One potential variable between nonspecific or mechanical low back pain and scoliosis is that the type of treatment that consistently works for a symmetrical spine may not work for an asymmetrical spine.

This retrospective study was created to describe the perceived responses of adults who were treated with PSSE. The Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) defines PSSE as consisting of: [5]

1. Auto-correction in three dimensions (3D)
2. Training in activities of daily living (ADL)
3. Stabilizing the corrected posture
4. Patient education

The stated basic objectives of PSSE are to: [6,7]

1. Stop curve progression at puberty (or possibly even reduce it)
2. Prevent or treat respiratory dysfunction,
3. Improve aesthetics via postural correction,
4. Prevent or treat spinal pain syndromes,

There are seven major PSSE schools that were reported in 2016. [5] The method used with the surveyed population is the BSPTS-Concept by Rigo, based on the principles of the Schroth Method. [5] There is limited research on the use and outcomes of PSSE for adults with scoliosis. The purpose of this study was to assess how adults perceived the use of PSSE after discharge in relation to their QoL and other factors for which they were seeking care such as dysfunction, pain and poor postural control.

## **Methods**

All methods were approved by a university internal review board. One clinic that specializes in the treatment of scoliosis was used for data collection. The clinic provided a list of all adult patients with scoliosis  $\geq 18$  years of age, who had received PSSE treatment over the last 7 years and had been discharged. A 10-question survey was created and uploaded to a secure server (Qualtrics). An email was sent to the subjects that both provide a link for the survey and informed the subjects that their submitted answers would be anonymous. The survey was sent three times over the duration of 3 months. Each subject that consented to take the survey could submit answers one time. The returned surveys were deidentified for data analysis.

## **Results and Discussion**

Fifty-seven adults (88.9% female) responded to the survey (55% response rate) with 67.2% being over the age of 55 years. The age of onset for the scoliosis diagnosis for this subject group was 48% in the teenage years and 23% learned of their condition after the age of 31 years (Figure 1). The majority (61.9%) felt that PT had moderately or significantly positively impacted their QoL. The most common number of PT visits ranged from 5 – 10, after which 71.9% of participants were either somewhat or very

confident in their ability to perform their PSSE program unsupervised at home. The most common frequency of HEP performance was 1-2 times per week (46.0%) for a duration of 5 – 40 minutes. Quantitative analysis of exercise adherence using a Spearman’s rho ( $r_s$ ) revealed positive associations between confidence in correctly performing the HEP with the perceived positive impact of the exercises ( $r_s = .45$ ,  $p < .001$ ), the greater frequency of performing the HEP ( $r_s = .30$ ,  $p = .024$ ) and greater time performing the HEP ( $r_s = .33$ ,  $p = .004$ ). The participants were also asked to rank order improvements perceived in the following areas: function, pain, well-being, physical appearance, Postural control, breathing and no impact or other (Figure 2). The ‘Other’ category ranked last in perceived improvement. The ‘Other’ option in this rank order had an open-ended response option. The responses are summarized in Table 1.

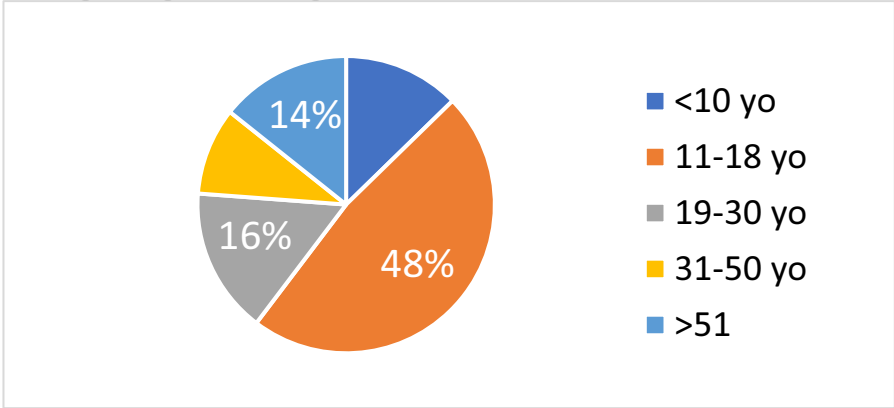


Figure 1: Age of first diagnosis

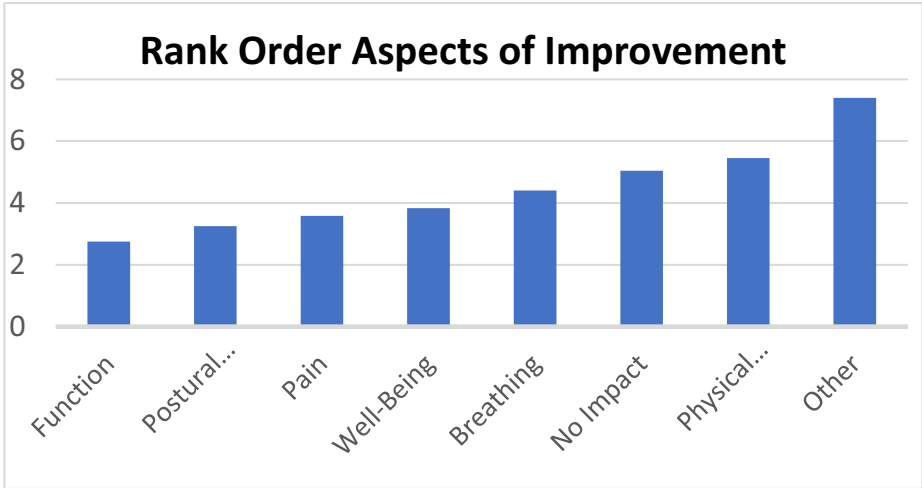


Figure 2: Aspects of improvements

Table 1: Summary of open-ended responses to ‘Other’ in the rank ordered perception of aspects of improvement.

N=7	Doing other exercise programs
N=3	I did the exercises until my problem was resolved
N=3	I don’t have all the right tools/equipment
N=2	Surgery for Scoliosis
N=2	Too difficult or need to have hands on training with PT
N=1	Other surgeries since scoliosis PT
N=1	Lack of motivation
N=1	It's more about awareness throughout the day

Physical Therapy is a profession that specializes in education of posture, joint protection, body mechanics as well as management of adults with back pain due to musculo-skeletal origin. While many adults with scoliosis are seeking care for back pain and decreased function, most current studies have found that PT has limited success in this area. However, most of these studies did not delve into what specific treatments or dosing of exercises was provided. This study found that a treatment regime of PSSE, specifically BSPTS-Concept by Rigo, was perceived by adults with scoliosis as beneficial. This perceived benefit also contributed to adherence with the HEP which is vital for maintenance and further improvement in symptoms and function. The implications of these patient perceptions is that PSSE should not be limited to only Adolescent Idiopathic Scoliosis (AIS), Juvenile Idiopathic Scoliosis (JIS) and kyphosis, but also include adult scoliosis.

The weaknesses of this study are:

- The lack of use of standardized tools to score the outcomes.
- The treatment was provided by one PT who specializes in PSSE at one clinic.
- The exercises used are not described or reproducible without continuing education training with BSPTS in the BSPTS-Concept by Rigo.
- Possible subject bias to answer for their PT’s benefit.
- The writing of the rank order question “no value” was unclear to some subjects.

Treatment using PSSE for adult scoliosis has reported value in this study. More correlations and associations with patient data would have also been beneficial, however it was important that subjects could answer truthfully and remain anonymous in this study. There needs to be a follow-up study with higher quality outcome measures. Areas of continued research could look deeper into the adult scoliosis vs. AIS home program guidance and adherence of frequency and duration of PSSE. Other studies, comparing multi-center outcomes of standardized PSSE to standardized traditional PT programs would also be beneficial. With higher evidence for PSSE in the treatment of adult scoliosis, a more universal acceptance of its use within the current medical model of care could possibly reduce the need for surgery and medications.

Conclusions and Significance

This retrospective analysis showed that with even small doses of exercise, 61.9% of adults felt that PT utilizing PSSE had moderately or significantly positively impacted their QoL. Adherence to a HEP is critical to the success of the program. Greater confidence in correctly performing the HEP was positively correlated with perceived impact, frequency and time spent exercising. The sample was limited to adults from one clinic that specializes in scoliosis and may not be generalizable to other clinics.



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# Chapter 10

## Surgical Treatment

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# Surgical results of Hybrid Mita method to idiopathic scoliosis: minimum two years follow-up

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**Abstract:** Hybrid Mita (Suzuki) method is a newly developed technique of scoliosis surgery. This concept consists of three components: rib mobilization, rod rotation maneuver and hook rotation maneuver, which does not require intra-operative CT scan with lower risk of screw malposition. The aim of this study is to evaluate the efficacies of this method for correction in scoliosis. : This is a retrospective observational study, consist of eighty-nine idiopathic scoliosis patients who underwent this method between 2009 and 2016 with minimum 2-years follow-up. The curve pattern, Cobb angle, hump height and angle, peri-operative events and complications were analyzed. The mean pre- and post-operative Cobb angle was 50.9° and 10.1°, respectively. The average correction rate was 80.5%. Hump height was reduced from 20.2 mm to 9.8 mm and hump angle reduced from 13.1° to 6.1° in average. The correction loss at the final follow-up was 0.3° in average. There were two local superficial infection cases, but there was no instrumentation failure such as malposition or dislodgement, or pseudarthrosis. This novel method is promising to provide excellent clinical correction to idiopathic scoliosis, which is no less than all pedicle screw constructs. The technique of the skillful utilization of hooks in spinal surgery should not perish from the stage.

**Keywords:** Idiopathic scoliosis, Hybrid constructs, Hook rotation maneuver, Rib mobilization

## Introduction

Hybrid Mita (Suzuki) method for adolescent idiopathic scoliosis (AIS) has been originally developed by Suzuki *et al.* in 2007 and the concept is proposed as a sum of three key procedures: rib mobilization, rod rotation maneuver and hook rotation maneuver, aiming to achieve better sagittal and coronal correction, derotation and rib hump correction.[1] The instrumentation consists of rods, hooks, sublaminar wires or tapes and pedicle screws (PSs). PSs are used only at the lower two or three vertebrae in principle. The major advantage of the new technique is that it does not require intra-operative CT scan, thus avoiding harmful radiation with lower risk of screw malposition.

In this concept, a technique of rod rotation maneuver[2] is modified by applying sublaminar wires tightened before rod rotation to maximize the translational and derotational force. From 2006, rib mobilization technique was introduced with release of costo-vertebral and costo-transverse ligaments at mid thoracic vertebrae bilaterally using

slightly curved osteotome and rib mobilizer, and the efficacy was proven by cadaveric experiments.[3] Hook rotation maneuver was developed in 2007, which was designed to enable satisfactory rotational correction and reducing rib hump. Usage of 7 mm width hooks and derotation device could provide strong vertebral rotation on the convex side, resulting in good hump correction. We hypothesize that this novel hybrid construct could be utilized for AIS correction. The purpose of this study is to evaluate the clinical efficacies of novel hybrid Mita (Suzuki) method.

## Methods

This is a retrospective observational study, consist of 89 post-operative scoliosis patients (10 males and 79 females) with a mean age of  $16.8 \pm 3.0$  years at surgery and a mean follow-up period was  $7.1 \pm 2.1$  years. Inclusion criteria were diagnosed as idiopathic scoliosis and patients who underwent hybrid Mita (Suzuki) method between 2009 and 2016 with minimum 2-years follow-up. The curve pattern, Cobb angle, hump height and angle, peri-operative events (operative time and estimated blood loss) and complications requiring revision surgery were analyzed. Statistical analyses were performed by Mann-Whitney U-test for continuous variables between pre- and post-operation.  $P < 0.05$  was considered as a statistically significant.

## Results and Discussion

The curve patterns were thoracic single major curve in 25 patients, thoracolumbar / lumbar single in 11, double major in 48 and triple major in five, respectively. The mean operation time was  $224.0 \pm 69.8$  minutes and the mean estimated blood loss was  $1071.9 \pm 535.7$  mL. The mean number of the fusion area was  $10.5 \pm 1.0$ . There were two local superficial infection cases, but there was no instrumentation failure such as malposition or dislodgement, or pseudarthrosis (Table 1). The mean pre- and post-operative Cobb angles were  $50.9^\circ \pm 10.0^\circ$  and  $10.1^\circ \pm 6.3^\circ$ , yielding correction rate of  $80.5 \pm 10.6\%$ . Hump height was reduced from  $20.2 \pm 8.1$  mm to  $10.1 \pm 6.3$  mm and the hump angle reduced from  $13.1^\circ \pm 4.3^\circ$  to  $6.1^\circ \pm 10.0^\circ$  in average (Table 2). In 53.8% of the patients, the residual scoliosis was less than  $10^\circ$ , whereas in 36.2%, it was between  $10^\circ$  and  $20^\circ$ . In 69.7% of the patients, the residual hump was lower than 15 mm of height. The mean correction loss angle between 6 months post-operation and final follow-up was  $0.3^\circ \pm 3.6^\circ$ .

In this study, we demonstrate that novel hybrid Mita (Suzuki) method can provide excellent correction to idiopathic scoliosis which is comparable to other constructs without harmful radiation.

Table 1. Peri-operative data

Total post-operative patients	n = 89
<b>Peri-operative Parameters</b>	
Operation Time (min)	224.0 ± 69.8
Estimated Blood Loss (mL)	1071 ± 535.7
Fused Levels	10.5 ± 1.0
<b>Complications</b>	
Superficial Infections	2 (2.3)
Dislodged or Malposition of Instrumentation	0 (0)
Pseudoarthritis	0 (0)
<b>Clinical Parameters</b>	
Post-operative Cobb Angle < 10°	49 (53.8)
Correction Loss > 7°	6 (6.7)
Post-operative Hump Height < 15mm	62 (69.7)

Table 2. Clinical parameters at pre-operative and final follow-up

	Pre-Operation	Final Follow-up	p
<b>Main Cobb Angle (°)</b>	50.9 ± 10.0	10.1 ± 6.3	< 0.01
<b>Hump Height (mm)</b>	20.2 ± 8.1	9.8 ± 6.7	< 0.01
<b>Hump Angle (°)</b>	13.1 ± 4.3	6.1 ± 3.7	< 0.01
<b>% Correction (%)</b>	-	80.5 ± 10.6	-
<b>Correction Loss (°)</b>	-	0.3 ± 3.6	-

All PS constructs has gained popularity over the last decade and several studies have demonstrated its superiority in the power of curve correction.[4,5] However, screw placement has potential risks including, neural injury, vascular injury, violation of the pleura and increased radiation exposure during screw placement.[6,7] Spinal cord around apical vertebrae is usually shifted to concave side[8,9] and screw malposition is reported at a rate of 15.7% in the systematic review by Hicks *et al.*[10] involving significant risk of iatrogenic spinal cord injury. Growing popularity of CT-based navigation enables surgeon to insert PS with ease and safe, although the accuracy is not always 100%, but rather increasing in risk of exposure to an excessive radiation,[11,12] with possible relevance to the morbidity of pertaining cancer.[13] The pros and cons of conventional hybrid construct are that it provides better sagittal correction than PS without intra-operative CT, although in coronal correction, PS construct is more powerful than hybrid construct.[14,15] Kuklo *et al.* reported that conventional hybrid construct has a higher complication and revision rate due to dislodged instrumentation or pseudoarthrosis.[16]

On the other hand, in this study, the novel hybrid Mita (Suzuki) method has only a few minor complications (2.3%) without any technical issues. Furthermore, post-operative hump height < 15mm was achieved in 69.7% of the patients, the mean coronal correction rate was 80.5%, the mean correction loss angle was 0.3° and the range of correction loss at final follow-up was within 8° in every case, suggesting that this hybrid

Mita (Suzuki) method can provide good scoliosis correction, which is no less than all PS constructs. Although this study is still a short-term follow-up and the subject group is rather small, we believe this is a very efficient, safe and useful procedure. We hope that the technique of the skillful utilization of hooks in spinal surgery should not perish from the stage.

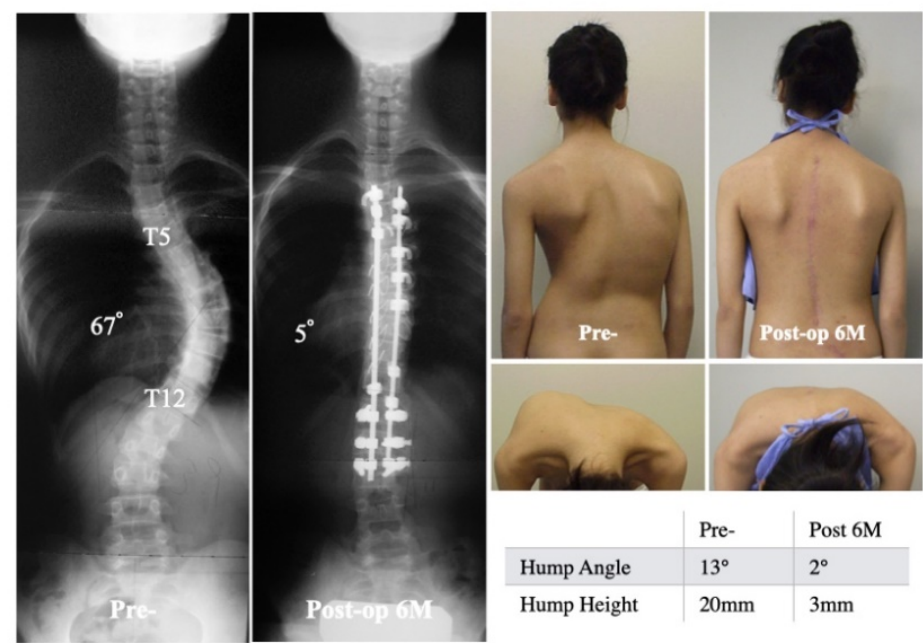


Figure 1. Representative case of a 12-year-old female with a 67° single thoracic major curve had an excellent scoliosis correction to 5°. Both hump height and angle were also corrected.

Conclusion and Significance

Hybrid Mita (Suzuki) method can provide excellent clinical correction to scoliosis comparable to other constructs. The most important advantage of this method is that it requires no intra-operative CT scan.

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# Spring distraction system to correct early onset scoliosis: 2 year follow-up results from 24 patients

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**Abstract:** Current surgical treatment options for Early Onset Scoliosis (EOS), with distraction- or growth-guidance systems, show limited growth and high complication rates. We developed the Spring Distraction System (SDS), which does not have to be periodically lengthened and which provides continuous corrective force to stimulate spinal growth. This study aimed to assess curve correction and maintenance, spinal growth, and complication rate following SDS treatment. All primary- and revision patients (conversion from failed other systems) with SDS and  $\geq 2$  years follow-up were included. Outcome measures were coronal Cobb angle, sagittal parameters, spinal length measurements and complications and re-operations. Radiographic parameters were compared pre-operatively, post-operatively and at latest follow-up. Spinal length increase was expressed as mm/year. Twenty-four skeletally immature EOS patients (18 primary and 6 revision cases) were included. There were 5 idiopathic, 7 congenital, 3 syndromic and 9 neuromuscular EOS patients. Mean age at implantation was 9.1 years (primary: 8.4; conversion: 11.2). Major curve improved from  $60.3^\circ$  to  $35.3^\circ$ , and was maintained at  $40.6^\circ$  at latest follow-up. Mean spring length increase during follow-up was 10.4mm/year. T1-S1 length increased 13.6mm/year and the instrumented segment length showed a mean increase of 0.8mm/segment/year. In total, 17 re-operations were performed. Ten re-operations were performed to treat 9 implant-related complications. In addition, 7 patients showed spinal growth that exceeded expected growth velocity; their springs were re-tensioned during a small re-operation. Spring distraction may be feasible as an alternative to current growing spine solutions. Curve correction and growth could be maintained satisfactory without the need for repetitive lengthening procedures. Complications and re-operations could not be prevented, which emphasizes the need for further improvement.

**Keywords:** Spring, Distraction, Early Onset Scoliosis, Growth friendly

## Introduction

Early Onset Scoliosis (EOS), if left untreated, can cause severe cardiopulmonary dysfunction.[1] Different “growth-friendly” implants have been developed that aim to control the scoliotic curve whilst allowing for continuous spinal growth, thereby supporting truncal development. Current distraction-based implants are lengthened intermittently, either with Traditional Growing Rods (TGR)[2] or with a Magnetically Controlled Growing Rod (MCGR).[3] These systems are not without disadvantages.

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First, these implants are stiff which may contribute to autofusion of the spine, leading to the “law of diminishing returns” seen in both TGR and MCGR.[4,5] Second, the rigid nature of these implants leads to increased implant stresses and subsequent implant failures. The MCGR in particular is a complex implant, is difficult to contour, and has many components that can fail. Recent studies have shown that less than 1 in 5 retrieved MCGRs still function as intended.[6,7] To address these drawbacks, we developed the Spring Distraction System (SDS), which employs the continuous distraction force of a compressed helical coil spring that is positioned around a standard rod that is allowed to slide at the proximal- or distal foundation (Figure 1).[8] The system does not require periodic lengthenings, and can be built into any given configuration, utilizing the advantages of both guided-growth and distraction-based systems.

We aimed to assess curve correction, growth and complication rate following SDS treatment during 2-year follow-up. Secondary aim was to compare outcomes between patients undergoing SDS as their first growth-friendly implant (primary cases) and patients that were revised to SDS after another (failed) system (conversion cases).

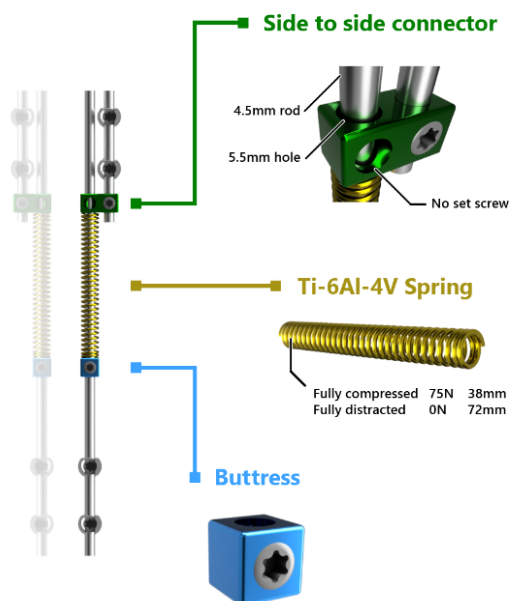


Figure 1. Spring Distraction System Concept

## Methods

### *Ethical review and eligibility criteria*

The current single-center prospective cohort study was approved by the Institutional Review Board of the UMC Utrecht. All skeletally immature EOS patients from 2016 onward with an indication for growing-rod surgery were eligible and included after informed consent. Patients whose current “growth-friendly” system had to be revised (e.g. because of implant failure) were also eligible for inclusion. For the current analyses, only patients with at least 2 years of follow-up were included.

### *Investigational medical device*

The key component of the SDS consists of a custom-made helical coil spring that was designed after extensive literature reviews to determine force safety limits and spinal growth. We chose a maximum spring force of 75 N, which is much lower than the distraction force of a single MCGR rod, and forces applied in TGR lengthenings. The titanium (Ti-6Al-4V) spring was manufactured by Lesjöfors AB (Karlstad, Sweden) to fit around a 4.5mm rod, with an uncompressed length of 72.0 mm, compressed length of 38.0 mm, spring constant of 2.15 N/mm and maximum compressed force of 75 N.

### *Spring Distraction System*

The SDS consists of three components (Fig 1): (1) A side-to-side connector with one oversized hole, (2) The spring that can be compressed and which provides a distraction force, and (3) A locking buttress that is used to compress the spring over the rod during surgery.

The spring and locking buttress are placed over the 4.5mm sliding rod that has 4-6 cm residual length. This rod bridges the scoliotic curve on its concavity and joins the short anchor rod in the parallel connector with an oversized hole to allow for sliding. By moving the buttress across the rod, toward the parallel connector, the spring can be compressed. Implanting bilateral springs doubles the distraction force to 150 N, while implanting two springs in series doubles the working length to 68 mm while the force remains unaltered. The convexity of the curve can either receive a similar distraction construct, or, when apical control is preferred, a passive sliding rod, fixed to the apex as described previously for MCGRs. To maintain distraction when full expansion has taken place, the spring can be re-tensioned by re-positioning the buttress in a small surgical procedure.

### *Outcome parameters*

The radiological outcomes were coronal Cobb angles, T5-T12 kyphosis, L1-S1 lordosis, T1-T12, T1-S1 and the Instrumented (i.e. all vertebrae bridged by the instrumentation) length. To determine spinal length, the freehand method was used by drawing a curved line through the midpoint of the upper and lower endplate of all involved vertebrae.[9] All measurements were performed on the pre- and post-operative radiographs, and on the radiographs at latest follow-up. Growth rates (mm/year) were calculated based on the difference between the post-operative and latest follow-up radiograph, thus excluding the length gain from initial surgery and definitive spinal fusion.[9]

## **Results and Discussion**

### *Patient demographics*

From 58 SDS patients, all patients who had at least 2 years of follow-up (N=24) were included and analyzed; 18 primary SDS patients and 6 conversion patients (3 TGR; 3 MCGR). Patient characteristics and comparison between primary- and conversion

cases are shown in Table 1. All EOS etiologies were represented. Mean follow-up was  $2.4 \pm 0.3$  years. No significant differences were seen between primary and conversion cases with respect to sex, EOS etiology, sagittal profile and follow-up length. As expected, primary patients were significantly younger ( $8.4$  vs.  $11.2$  years). They had larger primary curves at time of SDS surgery ( $65.0^\circ$  vs.  $45.9^\circ$ ) and had a higher number of instrumented segments ( $13.7$  vs.  $10.3$ ). Surgery was also significantly longer ( $230$  vs.  $123$  minutes), with higher blood loss ( $372$  vs.  $167$  mL) and they were discharged later ( $6.9$  vs.  $4.0$  days).

Table 1. Patient Demographics

	Primary SDS (N=18)	Conversion SDS (N=6)	p value	All patients (N=24)
Age at surgery (years)	$8.4 \pm 2.0$	$11.2 \pm 2.0$	0.006	$9.1 \pm 2.3$
Male	9 (50%)	2 (33%)	0.478	11 (46%)
EOS etiology			0.179	
Idiopathic	3 (17%)	2 (33%)		5 (21%)
Congenital	4 (22%)	3 (50%)		7 (29%)
Syndromic	2 (11%)	1 (17%)		3 (13%)
Neuromuscular	9 (50%)	0		9 (38%)
Pre-operative primary curve ( $^\circ$ )	$65.0 \pm 16.2$	$45.9 \pm 21.9$	0.032	$60.3 \pm 19.3$
Pre-operative T5-T12 kyphosis ( $^\circ$ )	$18.6 \pm 21.0$	$33.4 \pm 26.2$	0.173	$22.3 \pm 22.7$
Pre-operative L1-S1 lordosis ( $^\circ$ )	$47.8 \pm 13.4$	$52.5 \pm 15.2$	0.473	$48.9 \pm 13.7$
Surgery skin to skin time (minutes)	$230 \pm 62.6$	$123 \pm 34.3$	0.001	$203 \pm 73.5$
Estimated blood loss (ml)	$372 \pm 148$	$167 \pm 60.6$	<0.001	$318 \pm 15$
Instrumented levels	$13.7 \pm 3.1$	$10.3 \pm 2.7$	0.027	$12.8 \pm 3.3$
Time to discharge (days)	$6.9 \pm 2.1$	$4.0 \pm 1.3$	0.004	$6.2 \pm 2.3$
Follow-up length (years)	$2.4 \pm 0.3$	$2.3 \pm 0.3$	0.511	$2.4 \pm 0.3$

### Radiographic outcomes

For primary SDS patients, the main curve corrected from a mean of  $65.0^\circ$  to  $33.2^\circ$  (49% reduction), which was maintained at  $35.6^\circ$  at latest follow-up (Table 2). Conversion cases started with a mean primary curve of  $45.9^\circ$ , which was reduced to  $41.6^\circ$  (9% reduction), and increased again to  $55.8^\circ$  at latest follow-up. Nine patients showed additional curve correction during follow-up, seven patients showed a progression of the curve  $>10^\circ$  compared to post-operatively. For secondary curves, similar trends were seen. In primary cases, thoracic kyphosis decreased from a mean of  $18.6^\circ$  to  $16.7^\circ$  post-operatively. During follow up, a significant increase was seen to  $27.0^\circ$  ( $p=0.001$ ). Two patients with a congenital thoracic lordosis of  $>20^\circ$  due to posteriorly fused segments improved to a modest ( $5$ - $10^\circ$ ) thoracic kyphosis during follow-up. Conversion cases increased from a mean kyphosis of  $33.4^\circ$  to  $36.3^\circ$  post-operatively which increased significantly to  $46.0^\circ$  at latest follow-up ( $p=0.028$ ). Lumbar lordosis showed a similar pattern as thoracic kyphosis. Spinal height and length values are reported in Table 3. The mean freehand length gain was  $9.7$ mm/year for T1-T12,  $13.6$  for T1-S1 and  $0.8$ mm/segment/year for the instrumented segment, with only small differences between primary and conversion cases.

Table 2. Curve correction and sagittal profile

		Pre-operative	Post-operative	Latest follow-up	Change during follow-up
Primary curve (°)	Primary	65.0±16.2	33.2±11.8	35.6±15.6	+2.4 (-3.4 to +8.1); p=0.401
	Conversion	45.9±21.9	41.6±22.8	55.8±22.8	+14.2 (-0.1 to +28.5); p=0.051
	All patients	60.3±19.3	35.3±15.1	40.6±18.1	+5.3 (-0.14to 10.8); p=0.056
Secondary curve (°)	Primary	34.3±15.2	21.6±14.3	23.1±13.5	+1.5 (-1.9 to +4.9); p=0.363
	Conversion	24.4±7.86	21.0±9.66	23.9±6.80	+3.7 (-2.2 to +7.3); p=0.173
	All patients	31.6±14.1	21.4±13.0	23.3±11.9	+1.9 (-0.8 to +4.5); p=0.152
T5-T12 Kyphosis (°)	Primary	18.6±21.0	16.7±13.2	27.0±15.1	+9.7 (+4.0 to +16.3); p=0.001
	Conversion	33.4±26.2	36.3±26.2	46.0±27.7	+9.8 (+4.5 to +12.7); p=0.028
	All patients	22.3±22.7	21.6±18.8	31.7±20.2	+9.6 (+5.8 to +13.0); p<0.001
L1-S1 Lordosis (°)	Primary	47.8±13.4	41.2±10.4	49.6±19.4	+8.5 (+0.4 to +16.5); p=0.041
	Conversion	52.5±15.2	51.2±14.2	58.5±13.8	+7.0 (-3.7 to + 18.8); p=0.043
	All patients	48.9±13.7	43.7±12.0	51.8±18.3	+8.2 (+1.9 to +14.4); p=0.013

Table 3. Spinal Growth

		Pre-operative	Post-operative	Latest follow-up	Post-operative growth (mm/year)
T1-T12 freehand length (mm)	Primary	192±26.7	199±24.9	222±28.4	+9.8 (+7.6 to +12.0); p<0.001
	Conversion	209±28.6	214±30.6	235±35.9	+9.3 (+4.8 to +13.9); p=0.011
	All patients	196±27.6	202±26.6	225±30.1	+9.7 (+7.8 to +11.5); p<0.001
T1-S1 freehand length (mm)	Primary	319±41.4	330±37.8	362±44.4	+13.4 (+9.6 to +17.2); p<0.001
	Conversion	344±34.1	356±34.6	390±46.5	+14.2 (+3.7 to +24.7); p=0.029
	All patients	325±40.6	336±38.1	369±45.7	+13.6 (+10.2 to +17.0); p<0.001
Instrumented freehand length (mm)	Primary		259±65.0	286±75.1	+0.9/segment (+0.6 to +1.2); p<0.001
	Conversion	NA	220±39.0	241±41.0	+0.6/segment (+0.3 to +1.0); p=0.018
	All patients		249±61.3	274±70.2	+0.8/segment (+0.6 to +1.1); p<0.001
Spring length (mm)	Single spring (N=9)		40.9±3.7	56.3±9.3	+6.5 (+3.6 to +9.4); p=0.001
	Double spring (N=15)	NA	83.7±7.6	113±15.3	+12.7 (+9.8 to +15.6); p<0.001
	All patients		67.7±22.1	91.6±30.9	+10.4 (+8.0 to +12.7); <0.001

Complications and re-operations

There were no intra-operative complications, patients recovered well and could be discharged after a mean of 6.2±2.3 days. The springs did not show any failures in terms of fracture or dysfunction due to tissue encapsulation. During ≥2 years of follow-up, 17 re-operations were performed in 13 patients. Ten re-operations were performed for 9 implant-related complications in 8/24 patients (33%). Implant prominence was the most common complication, and occurred in 3 patients. In addition to the complications, 7/24 patients (29%) needed a (small) re-operation for re-tensioning of the spring, after a mean of 1.9±0.6 years. This was due to unexpected length gain immediately after insertion of

the system (tissue relaxation/creep), and/or a spinal growth rate that exceeded expectations.

## Conclusion and Significance

The Spring Distraction System appears to be a promising technique for surgical treatment of EOS. Curve correction in primary cases was 50% and could be maintained for at least 2 years. Mean T1-S1 length gain during follow-up was 13.6 mm/year. Complications and reoperations could not be prevented, but there are opportunities to decrease this further.

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# Spine growth modulation with titanium implant: comparisons to observation and bracing in early adolescent idiopathic scoliosis

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**Abstract:** Outcomes of a pilot study of spine growth modulation (GM) were compared to those of untreated and braced patients from a concurrent bracing effectiveness trial (BrAIST). The purpose of this study was to determine probabilities of progression (PP) to fusion indications ( $\geq 45^\circ$ ) in a cohort of subjects who underwent GM surgery, and to compare GM outcomes to those of matched BrAIST subjects. Secondary analyses were conducted comparing two prospective longitudinal studies. In one, a vertebral GM system was implanted in 6 highly skeletally immature AIS patients. The control group provided by BrAIST was comprised of a subset of untreated or braced subjects that fit the eligibility criteria of the GM study. GM outcomes were compared to predictions from two prognostic logistic regression models derived from BrAIST to estimate risk of curve progression to  $\geq 45^\circ$ . If the GM patients were untreated, PPs ranged from 68-98%. If braced for 18 hours/day, progression was expected in two of six, one with a PP of 71%. This latter patient not only did not progress, his curve decreased  $>20^\circ$ . In the matched cohort, two were untreated and quickly progressed, whereas two were braced and did not progress. Therefore, the bracing models and matched cohort confirmed the initial assumption that all GM patients were at high risk if untreated. They also supported the probable benefit of the GM system, as 3 of 6 benefited from GM relative to predictions for untreated patients, and one of 6 benefited compared to predictions for highly compliant braced patients.

**Keywords:** AIS, Vertebral growth modulation, Bracing, Prognostic models

## Introduction

Assessing curve progression risk in adolescent idiopathic scoliosis (AIS) is essential to minimize both under- and over-treatment. Very skeletally immature patients have long been known to be at particularly high risk, yet little evidence exists of treatment efficacy for this subgroup.

A pilot clinical safety study of a vertebral growth modulation system (GM) using titanium clip-screw constructs was conducted in 6 patients with early AIS, the maximum number allowed under US FDA Investigational Device Exemption (IDE) (HemiBridge NCT01465295, FDA R01). Patients were followed to 5 years or skeletal maturity.[1] Outcomes were variable, ranging from progression to over-correction. Although all

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patients were considered high-risk according to the literature at the time, evaluation of the system's effect relative to no treatment[2-6] or to bracing[7-10] remains difficult without matched comparisons.

A concurrent multicenter bracing effectiveness study (BrAIST NCT00448448, NIH NIAMS) showed that bracing was effective for many, but not all, patients.[11] Recently, prognostic models derived from BrAIST have been reported for untreated and for braced patients.[12,13]

The purpose of this study was to determine predicted probabilities of progression (PP) to fusion indications in the GM cohort based on prognostic models derived from BrAIST,[12,13] and to define a subgroup from BrAIST best matched to GM subjects to compare outcomes. The expectation was that GM patients would have better outcomes than predictions and matched cohorts.

## Methods

The experimental design was secondary analysis comparing two prospective longitudinal studies, each conducted under stringent protocols. The GM study was case series from first human use (IRB, FDA approved). The BrAIST study was composed of two arms, randomized and preference.[11]

The vertebral GM system was implanted in 6 highly skeletally immature AIS patients, the maximum allowed by FDA for a Phase I IDE study.[1] Eligibility criteria were chosen to include only those patients very highly likely to progress to fusion indications as best known at the time: diagnosis of idiopathic scoliosis, major thoracic curve, Lenke Type 1A or 1B, magnitude 25°-40° measured by Cobb method, T3-T12 kyphosis ≤40°, chronologic age ≥10 years, and, if female, premenarchal at screening examination. For bone age, as determined by radiographs of the left hand and wrist using the Atlas Matching method, criteria were from ≥8 years + 10 months to ≤13 years for females, and from ≥10 years and ≤15 years for males. Skeletal immaturity was classified as Risser grade 0 (R0) plus open triradiate cartilages (OTRCs). Clinical diagnosis was determined from standing posterior-anterior radiographs with end vertebrae between or including T3 and L1. The simplified skeletal maturity scale (SMS)[5,6] was determined later from the hand radiographs.

For the BrAIST trial, 383 patients were enrolled, of which 306 were followed to final outcomes at skeletal maturity.[12] Brace wear with a rigid thoracolumbosacral orthosis was prescribed for ≥18 hours/day. Compliance was monitored with a temperature logger and average wear time was determined for each 6-month interval. Inclusion criteria were diagnosis of AIS and current indications for brace treatment: aged 10-15 years, Risser 0-2, and magnitude of largest curve of 20°-40°. Outcomes were defined as either progressing to ≥45° or reaching skeletal maturity without reaching 45°. Two prognostic logistic regression models were then derived from final BrAIST outcomes to estimate risk of curve progression to fusion indications (≥45°).[12,13] Internal and external validity were evaluated using jackknifed samples of the BrAIST data set and independent cohort. One model used SMS for the maturity marker and one used Risser and the status of the triradiates for brace wear of different doses, 0 to 18 hours/day. Additional parameters included curve magnitude, as well as apex location for the SMS model, and age for the Risser model. The prognostic models were applied to each of the GM subjects to determine predicted probabilities of progression under the assumption that each was untreated or braced for an average of 0, 6, 12, or 18 hours/day.

Further context for the GM outcomes was provided by a control group defined from BrAIST comprised of a matched cohort of untreated or braced subjects, each of whom fit the inclusion criteria of the GM study, including OTRCs. Outcomes were compared between the 3 groups, GM, untreated, and braced, by changes in curve magnitude over time.

Results and Discussion

Predicted probabilities of progression to fusion indications for no treatment were 87% (range 68%-94%) for the SMS model, and 92% (range 86%-98%) for the model based on Risser with 0 hours/day average wear time (Table 1). PPs from the models were within 10% of each other for all but the subject with the lowest PPs (Subject 5) from each model. The probabilities at 6, 12, and 18 hours/day were 81% ( $\pm$  9), 62% ( $\pm$  14), and 39% ( $\pm$  17), respectively. For bracing, a PP  $\geq$ 40% is considered significant risk. If the GM patients had been treated with 18 hours of bracing, progression to  $\geq$ 45° was expected in Subjects 1 and 4, with predicted probabilities of 40% and 71% respectively (Table 1). Yet only Subject 1 had a poor outcome. Not only did the curve of Subject 4 not progress (Figure 1), it decreased  $>$ 20° despite very high progression probability with very high bracing compliance.

Table 1. Demographics and outcomes of GM subjects with comparisons to BrAIST model predictions for GM subjects under the assumption that each was braced for an average of 0 or 18 hours/day.

GM Vertebral Growth Modulation		GM Pre-Tx Maturity		GM Pre-Tx Curve		GM Post-Tx Curve	BrAIST -Risser Model Predicted Probability of Progression to $>$ 45° (PP) prior to skeletal maturity	
Subject	Sex	Age (years)	SMS	Cobb angle (deg)	Cobb angle (deg)		If untreated: 0 hrs/day brace wear	If braced: 18 hrs/day brace wear
1	F	13	2	35	$>$ 45		0.94	0.4
2	F	12.6	2-3	30.5	32		0.86	0.22
3	M	11.7	2-3	35	$>$ 45		0.92	0.35
4	M	10.6	1-2	36	9		0.98	0.71
5	F	10.1	3	31	39		0.91	0.32
6	M	14.9	3	38.5	$>$ 45		0.91	0.33

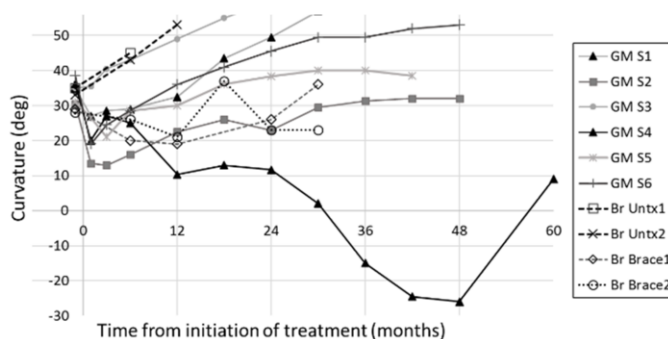
For the matched cohort, four BrAIST subjects best matched the full GM eligibility criteria. Two were untreated and two were braced. The two untreated progressed to 45° in 6 months, whereas the two braced subjects did not progress more than 10° in 30 months. Both used the brace an average of 12 hours per day.

Superposition of the BrAIST and GM longitudinal sequences (Figure 2) showed that one GM subject progressed at the same rate as the two who were untreated. Two others decreased initially, then progressed at a similar rate, reaching fusion indications about one year later. Another two curves did not change more than 10° in 3 to 4 years, like the 2 braced subjects. Notably, the one outlier was GM Subject 4 whose curve gradually decreased, eventually overcorrecting locally, which led to removal of the proximal three

implants. This was the subject with a predicted probability of progression of 71% if braced 18 hours/day.



**Fig. 1.** Growth modulation patient (S4, 18 mos post-op). Curve decreased from pre-operative magnitude of 36°.



**Fig. 2.** Major thoracic curvature versus time from initiation of treatment for GM (solid lines), untreated (dashed lines), and braced (dotted lines) subjects. The two braced subjects (Brace1, Brace2) both wore their braces an average of 12 hours/day.

Limitations of this study include small sample sizes. Few BrAIST subjects were found with triradiate cartilages clearly open in addition to the other eligibility criteria. Several factors other than those investigated here affect outcomes, including fit for both bracing and implants. Optimized fit between implants and vertebrae has been hypothesized to improve GM success rates;[1] a larger implant size and changes to screws and titanium surface characteristics have been approved for a Phase II study. Strengths of this study include that both underlying studies were prospective and longitudinal, conducted under stringent protocols, and so afforded a high level of evidence.

This study agrees with a few others that AIS patients who are Risser grade 0 are at risk for surgery despite compliant brace wear. One previous study reported that in their R0 patients, an average daily wear time of 12.9 hours did not prevent surgery, and further, patients with open triradiate cartilages were at highest risk. Specifically, those with OTRCs and curves 30°-39° had a rate of progression to surgery of 70%. [14] Another study reported that thoracic curves were at greater risk for brace failure than lumbar curves despite similar initial curve magnitudes and average daily brace wear time. Thoracic curves, especially in R0 patients, were less responsive to treatment with a TLSO in their study even if the patient was compliant. [15] Although the present and these prior studies all include small subgroups, the combined results support the assumption that the GM subjects were all likely to progress, and additionally, were likely more resistant to bracing than patients with other curve types of the same initial size.

## Conclusion and Significance

This study confirmed that the GM eligibility criteria included only those patients with curves highly likely to progress. All 6 subjects were at very high risk if untreated

according models and compared to the matched cohort. In addition, GM probable benefit was supported, as three of six patients benefited relative to no treatment, and one benefited compared to even highly compliant bracing. Emerging prognostic models for bracing are likely to improve specificity of comparisons for the next tests of different brace types and conditions, as well as this or other GM systems, towards the goal of avoiding spine fusion in a larger proportion of very skeletally immature AIS patients with moderate thoracic curves.

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# Chapter 11

## Quality of Life and Functional Outcomes

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# Convergent validity, ceiling, and floor effects of the English-ISYQOL against established quality of life questionnaires (SRS-22r and SAQ) and curve angles in adolescents with idiopathic scoliosis

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**Abstract:** Scoliosis significantly impacts Quality of Life (QOL). Current quality of life questionnaires for adolescents with idiopathic scoliosis (AIS) have limitations. A new questionnaire for measuring QOL in AIS called the Italian Spine Youth Quality of Life (ISYQOL) has been developed to address these limitations but the English translation has not yet been validated. To determine the ceiling and floor effects, and the convergent validity of the ISYQOL questionnaire against established QOL questionnaires and Cobb angle in AIS. One hundred consecutive females with AIS, (10-18 years old), treated non-operatively. The English translation of the ISYQOL was compared to the following established questionnaires: Scoliosis Research Society-22r and the Spinal Appearance Questionnaire. The participants were 100 females (13.89 $\pm$ 1.8 years) with 28.75 $\pm$ 13.9° curve angles. The convergent validity of the ISYQOL score (60.3 $\pm$ 12.44) was supported by significant correlation with the SRS-22r total score, function, pain, self-image, and mental health scores ( $r = 0.70, 0.54, 0.57, 0.52$  and  $0.50$ , respectively), and with the SAQ general, waist, and expectations domains ( $r = -0.6, -.52$ , and  $-0.56$ , respectively). Correlation with the Cobb angle was ( $r = -.37$ ) (see Table 1). No ceiling effect was observed in the ISYQOL. Ceiling effects were observed for the SRS-22r and the SAQ. The ISYQOL demonstrated evidence of convergent validity. This study supports its suitability for QOL research in AIS. ISYQOL appears more likely to detect changes in evaluative studies than the SRS-22r and the SAQ.

**Keywords:** Scoliosis, Quality of life, Convergent Validity, Adolescents.

## Introduction

Adolescent idiopathic scoliosis (AIS) is the most common form of scoliosis for those whose age ranges from 10 to 18.[1] The prevalence of AIS is between 2-3% in this age group.[2] AIS corresponds to nearly 80% of all spine deformity cases for adolescents and is defined as “a structural, lateral, rotated curvature of the spine that arises in

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otherwise healthy children at or around puberty”.[3,4] Despite decades of research, the etiology of AIS remains unknown.

With AIS, the risk of scoliosis-related health problems developing into adulthood life increases, resulting in decreased quality of life, cosmetic deformity, pain, and progressive functional limitations, especially if the curve magnitude is 30° or more at skeletal maturity.[5] If the curve is over 50°, it is almost certain that the curve will progress into adulthood, leading to deterioration in health-related quality of life.[5]

*Health-related quality of life* is a measure of the effects of a disease or a treatment on the physical, psychological, and social domains of functioning and well-being for a patient.[6] However, current outcome measures for *health-related quality of life* for patients with AIS show limitations in their measurements properties. The Scoliosis Research Society (SRS-22) questionnaire was not developed with input from patients and was initially created to measure QOL in candidates for surgery (i.e. patients with severe scoliosis).[1,7,8] In a study of 173 adolescent females with AIS treated conservatively, nine items of the SRS-22r had major ceiling effects ( $\geq 50\%$ ), (high proportion of participants with the best possible score), and 11 had moderate ceiling effects ( $\geq 20\%$ ).[8] Therefore, the SRS-22r may not accurately assess patients with milder forms of scoliosis. Additionally, the SRS-22r was not developed using modern scaling techniques such as Rasch analysis.[7]

The Spinal Appearance Questionnaire (SAQ) assesses the perception patients have regarding their own appearance, as viewed from the back. This is not only impractical, but this view may also be of lesser importance to the patient compared to their appearance as viewed from the front.[9] Furthermore, the SAQ was also not developed with Rasch scaling, which ensures that the scores for the items are equally distributed.[7,9] This ensures that a measure has the attributes of being a continuous measurement, theoretically providing more power in analyses and the ability to detect change.[7] Lastly, the SAQ was not developed with patient input, which may therefore affect content validity.[9] Recently, Carreon et al.[10] developed a revised version of the SAQ named the Spinal Appearance Questionnaire version 1.1 (SAQ v1.1). Using factor analysis, they revised the SAQ into 14 items loaded onto two factors. The sum of the first 10 items make up the Appearance domain, and the sum of the last 4 items make up the Expectations domain. In contrast to the original version of the SAQ, the SAQ v1.1 has a total score that may facilitate a comparison between patients’ perceived appearance in studies using different tools.

New questionnaires have been developed to address limitations of the SRS-22 and the SAQ. The Italian Spine Youth Quality of Life (ISYQOL) questionnaire was developed using Rasch analysis, and items on the ISYQOL were developed with input from patients, families, and clinicians to accurately assess changes related to treatment, ranging from conservative to surgical, for patients with varying levels of disorder.[11] The input from patients and families is important to ensure that the items of the questionnaire are comprehensive and related to actual patient concerns. The ISYQOL has been translated to English from Italian using consensus provided by four team members. This translated ISYQOL was then reviewed by three Italian collaborators for compatibility with the original version.[12] The Italian collaborators found the English version to adequately represent the Italian version. The internal consistency of the ISYQOL has been tested in adolescents with idiopathic scoliosis and meets recommended internal consistency standards ( $\alpha = 0.79 - 0.84$ ).[12]

Given the problems with existing measurements such as the SRS-22r and the SAQ v1.1, there is a need to assess the measurement properties of the ISYQOL. Such analysis



may help determine whether these new measures adequately resolve the limitations presented in existing measurements used for patients with AIS. Additionally, metrological evidence may aid in choosing the best measures for assessing efficacy of AIS operative and non-operative interventions in both clinical practice and research. The objective of this study was to determine the ceiling and floor effects, and the convergent validity of the ISYQOL questionnaire against established QOL questionnaires and Cobb angle in AIS.

## Methods

### *Sample*

Participants were recruited for this study from the Stollery Children's Hospital while attending routine scoliosis clinic visits. Informed consent was obtained from eligible participants and their legal guardians. This study, including its consent documentation, was reviewed and approved by the University of Alberta Health Research Ethics Board (Pro00073569). A total of one-hundred participants (n=100) were recruited. Inclusion criteria for this study included: having an active diagnosis of idiopathic scoliosis, be of 10-18 years of age, have curve severity over 10°, and being fluent in English. Exclusion criteria included: having a history of spine surgery, having a history or active diagnosis of other diseases that might affect quality of life and/or torso appearance, or having history of trauma in the torso or lower extremities.

### *Outcome measures*

#### *Scoliosis Research Society-22 Refined Questionnaire (SRS-22r)*

The Scoliosis Research Society-22 refined questionnaire (SRS-22r) is the most commonly used instrument for measuring HRQOL in patients with scoliosis.<sup>13</sup> It consists of 22 questions covering five domains: pain, self-image, function, mental health, and satisfaction with management. Scores range from 1 to 5 per question, and these scores are averaged to produce domain scores and a total score.[13] Higher scores on the SRS-22r indicate better quality of life. The SRS-22 demonstrated acceptable reliability (ICC = 0.85 to 0.96) and concurrent validity ( $r > 0.70$ ) compared to the Short Form 36 (SF-36). However, 56.9% of respondents were given the highest score possible, showing that this assessment has potential ceiling effects and floor effects for patients with post-operative idiopathic scoliosis.[13] The SRS-22 has been refined to improve the internal consistency of its function domain, increasing to  $\alpha=0.67$  to 0.78 following changes.[14]

#### *Spinal Appearance Questionnaire Version 1.1 (SAQ v1.1)*

The Spinal Appearance Questionnaire version 1.1 (SAQ v1.1) is a modified version of the SAQ. It consists of 14 items. The first ten items are related to the 'Appearance' domain and the last four items are related to the 'Expectations' domain. The ten items related to the appearance domain are as follows: body curve, rib prominence, flank prominence, head-chest-hips, position of head over hips, shoulder level, shoulder blade rotation, shoulder angle, head position, and spine prominence. The four items related to the expectations domain are as follows: 'I want to be more even'; 'I want to have more

even shoulders'; 'I want to have more even hips', and 'I want to have a more even waist'. For the 'Appearance' domain, response options are provided as drawings ranging from mild (score of 1) to severe (score of 5). The 'Expectations' domain features response options ranging from 'not true' (score of 1) to 'very true' (score of 5). Answers are subsequently summed to provide a score ranging from 10 to 50 for the 'Appearance' domain and ranging from 4 to 20 for the 'Expectations' domain. The SAQ v1.1 total score is calculated by summing the total scores of both domains.[10] The best possible total score for the SAQ v1.1 is 14, related to better QOL and more positive perception of scoliosis related appearance and the worst possible score is 70.[10] In a study conducted by Carreon and colleagues, 1,802 adolescents with AIS were given the SAQ v1.1 and their results suggested that the SAQ v1.1 had good reliability (Cronbach's  $\alpha \geq 0.88$ ; test-retest correlation  $\geq 0.81$ ) and convergent validity as it relates to major curve magnitude ( $r=0.32 - 0.36$ ).[10]

### *Italian Spine Youth Quality of Life Questionnaire (ISYQOL)*

The ISYQOL is a new patient reported outcome measurement (PROM) for health-related quality of life in adolescents with idiopathic scoliosis.[12] The ISYQOL aims to accurately assess changes related to treatment, ranging from conservative to surgical, for patients with varying levels of disease.[12] Items of the ISYQOL were generated following a content analysis of the concerns expressed by patients, parents, and scoliosis specialists from an online forum.[12] The ISYQOL was developed using Rasch analysis, which ensures that the items are equally distributed and serves as a continuous measurement.[12] Studies analyzing the measurement properties of the ISYQOL are promising. For example, Caronni and colleagues concluded that ISYQOL performs better than the SRS22, having better validity and ability to detect the impact of disease severity on health-related quality of life.[2,3]

### *Statistical Analysis*

The following statistical analyses were performed:

- Pearson correlation coefficients were used to evaluate the correlation between questionnaire scores and each radiographic measurement. A one-tailed significance level was used for hypothesis testing given the assumption that larger radiographic measurements are related to poorer quality of life and more negative perception of self-image.[15,16]
- Ceiling and floor effects were quantified for each score by calculating the percentage of participants obtaining the best and worst possible scores, respectively.[7]

Results related to the satisfaction domain of the SRS-22r were not analyzed because patients did not have a long history of care (many were being evaluated for their first visit).

## **Results and Discussion**

One-hundred participants were recruited for this study. All were female ( $n = 100$ ), had a mean age of  $13.9 \pm 1.8$  years, and a mean curve angle of  $29^\circ \pm 14^\circ$ . Sixty-three ( $n =$

63) received conservative treatment whereby 38 had a brace and 25 received exercise treatment. The mean QOL as scored on the SRS-22r and SAQ v1.1 was  $4.13 \pm 0.53$  and  $27.17 \pm 9.15$ , respectively.

The ISYQOL score ( $60.3 \pm 12.4$ ) had a significant correlation with the SRS-22r Total, function, pain, self-image, and mental health scores ( $r = 0.70, 0.54, 0.57, 0.52$  and  $0.50$ , respectively); it also had correlation with the SAQ v1.1 Total score ( $r = -0.53$ ), Appearance ( $r = -0.46$ ), and the Expectations domains ( $r = -0.50$ ).

Only 2% of the participants scored the highest possible ISYQOL score and no participants scored the lowest possible score. In contrast, the percentage of ceiling effects in the affected domains of the SRS-22r was as follow: Function= 19% and Pain= 18%. Ceiling effects for the SAQ v1.1 domains were as follows: Total score= 3%, Appearance= 5%, and Expectations= 14%. The Expectations domain of the SAQ v1.1 demonstrated a floor effect of 10%.

Table 1. Correlations between the English ISYQOL score and SAQ and SRS-22r scores

	ISYQOL
SAQ - Appearance	-0.46**
SAQ - Expectations	-0.50**
SAQ - Total	-0.53**
SRS22r - Function	0.54**
SRS22r - Pain	0.57**
SRS22r - Self-Image	0.52**
SRS22r - Mental Health	0.50**
SRS22r - Total	0.70**

\*\* . Correlation is significant at the 0.01 level (2-tailed)

## Conclusion and Significance

Overall, the ISYQOL demonstrated convergent validity by significantly correlating with the SAQ v1.1. Similarly, it demonstrated convergent validity by significantly correlating with the SRS-22r. This study supports the use of the English ISYQOL for QOL research in AIS. Additionally, the ISYQOL appears to be better at detecting changes compared to the SRS-22r and the SAQ V1.1 as its is free from ceiling and floor effects.

A previous study concluded that the ISYQOL has better known-groups validity and is more sensitive at detecting impact of disease severity on HRQOL in adolescents with scoliosis compared to the SRS-22.[17] Additionally, our lab found the internal consistency of the translated ISYQOL to meet the recommended standards for internal consistency in adolescents with idiopathic scoliosis ( $\alpha = 0.79 - 0.84$ ).[12]

However, before recommending the wider utilization of the ISYQOL, future studies are recommended to evaluate test-retest reliability of the ISYQOL to assess the stability of its scores and responsiveness to assess its ability of these questionnaires to detect change.

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# Loss of body height due to severe thoracic curvature does impact pulmonary testing results in adolescents with idiopathic scoliosis

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**Abstract:** A standing body height is a variable used to calculate pulmonary parameters during spirometry examination. In adolescents with idiopathic scoliosis, the loss of the body height is observed, and it may potentially influence the results of pulmonary testing. The study aimed to analyze pulmonary parameters in adolescents with idiopathic scoliosis in relation to the measured versus the corrected body height. Preoperative pulmonary testing and radiographic evaluation were performed in 39 children (29 females, 10 males) aged 12-17 years. Forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) were measured. The single best effort was analyzed. Thoracic Cobb angle ranged 50°-104°. Corrected body height was calculated according to the Stokes' formula. The subgroup analysis was performed for the subjects with curves 50°-74° (N=26) versus 75°-104° curves (N=13). Mean measured body height was 166.1±9.0 cm versus 168.9±8.9 cm mean corrected body height. The %FVC obtained for the measured height was significantly higher than obtained for the corrected height: 84.6% ±15.6 vs. 81.6% ±15.6,  $p<0.001$ . The %FEV1 obtained for the measured height was significantly higher than obtained for the corrected height: 79.8% ±16.3 vs. 77.35% ±15.9,  $p<0.001$ . The subgroup analysis revealed significant differences in %FVC and %FEV1 calculated for the measured versus the corrected body height,  $p<0.001$ . Corrected body height significantly influences the results of pulmonary parameters measurement. In consequence, it may influence the analysis of the pulmonary status of children with idiopathic scoliosis.

**Keywords:** idiopathic scoliosis, body height, pulmonary function test, Cobb angle

## Introduction

Body height measured in a standing position is a variable used to calculate pulmonary parameters during spirometry examination.[1] However, in adolescents with idiopathic scoliosis, the loss of body height due to deformation of the spine is observed, and it may potentially influence the results of pulmonary testing.

In previous studies, the authors presented regression equations relying on the Cobb angle values that may be used to calculate the loss of the body height.[2-5] All of

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the methods are used in clinical practice; however, none is considered a gold standard for establishing the corrected body height in patients with idiopathic scoliosis.

The study aimed to analyze pulmonary parameters in adolescents with idiopathic scoliosis in relation to the measured versus the corrected body height.

Methods

Preoperative pulmonary testing and radiographic evaluation were performed in 39 children (29 females and 10 males) aged 12-17 years (mean 14.2 ±1.6).

According to the Cobb method, angles of the thoracic curvature were measured on the standard anteroposterior radiographs of the spine.[6] Based on the thoracic Cobb angle value, the patients were divided into 2 subgroups: subgroup I. included patients with moderate scoliosis, Cobb angle within the range of 50°-74° (N=26); subgroup II. included patients with severe scoliosis, Cobb angle within the range of 75°-104° (N=13).

The corrected body height was calculated as a sum of the measured standing body height and the height loss calculated according to the Stokes' formula.[5]

Forced Vital Capacity (FVC) and Forced Expiratory Volume in 1 second (FEV1) were measured 3 times in a sitting position using the turbine spirometer. The single best effort was analyzed. Percentages of the predicted values of FVC (%FVC) and FEV1 (%FEV1) for the measured and the corrected body height were obtained. The Global Lung Function Initiative (GLI 2012) data were used as reference value.[7]

The values of the loss of body height were calculated in Excel (Microsoft). The mean value, standard deviation, and range of the parameters were calculated. Normal data distribution was analyzed with Shapiro-Wilk test. The Student's-t Test was used to determine the significances between pulmonary parameters (%FVC and %FEV1) calculated according to the measured and the corrected body height. The analysis was performed with Statistica Software (TIBCO Software Inc.).

Results and Discussion

The Cobb angle of the thoracic curve 50°-104°, mean 69.8°±12.4°. Mean values of the measured, the corrected body height, and mean loss of the body height calculated using the Stokes formula are presented in Table 1.

Table 1. Mean values of the measured, the corrected body height and mean loss of the body height of the patients

Mean measured body height [cm]	Mean corrected body height [cm]	Mean height loss [cm]	p-value
166.1±9.0 (148-182)	168.9±8.9 (151.2-185.8)	2.8±1.1 (1.5-6.4).	p<0.001*

All values are presented as mean, standard deviation, minimum and maximum in the brackets.\*- value statistically significant. Mean FVC was 3.25L ± 0.84 (range 1.58-5.47). Mean FEV1 was 2.67L±0.68 (range 1.28-4.04).

Comparative analysis of the study group and subgroups based on the percentages of predicted values of the pulmonary parameters (%FVC and %FEV1) calculated according to the measured versus the corrected body height is presented in Table 2.

Table 2. Analysis of the pulmonary parameters calculated according to the measured versus the corrected body height

Parameter	Measured body height	Corrected body height	Mean difference	p-value
Thoracic Cobb angle 50°-104° N=39				
%FVC	84.6 ± 15.6 (52.9-116.3)	81.6 ± 15.6, (49.7-114.4)	3.0 ± 1.24 (0.4-5.8)	p<0.001*
%FEV1	79.8 ± 16.3 (40.2-107.9)	77.3 ± 15.9 (39.4-103.5)	2.73 ± 1.2 (0.8-5.1)	p<0.001*
Thoracic Cobb angle 50°-74° N=26				
%FVC	86.1 ± 13.0 (62.7-114.0)	84.3 ± 13.6 (61.3-114.4)	2.3 ± 0.7 (0.4-3.4)	p<0.001*
%FEV1	82.0 ± 14.3 (40.2-104.7)	79.8 ± 13.6 (39.4-102.6)	2.2 ± 1.0 (0.8-5.1)	p<0.001*
Thoracic Cobb angle 75°-104° N=13				
%FVC	81.3 ± 20.0 (52.9-116.3)	77.05 ± 19.4 (49.7-111.2)	4.28 ± 0.9 (2.8-5.8)	p<0.001*
%FEV1	75.9 ± 19.8 (46.9-107.9)	72.1 ± 19.2 (44.2-103.5)	3.7 ± 0.9 (2.4-5.0)	p<0.001*

%FVC-percentage of predicted value for FVC; %FEV1- percentage of predicted value for FEV1. All values are presented as mean, standard deviation, minimum and maximum in the brackets.\*- value statistically significant

The determinants previously identified as the ones that may contribute to the height loss in patients with idiopathic scoliosis were: Cobb angle value, curve length, curve inclination, and a number of the vertebrae forming the curve.[2-5,8] However, most of the equations are based on the Cobb angle values.[2-5]

Tyrakowski et al.[9] concluded that no overall agreement between analyzed four methods: Bjure, Stokes, Kono, Ylikoski existed. Gardner et al.[10] analyzing methods used to calculate the loss of the body height in patients with idiopathic scoliosis recommended the Kono and Stokes formulas as the most valid.

Stokes[5] established the formula by analyzing the relationship between the Cobb angles, spinal height, and spinal length on radiological examinations of the 387 patients diagnosed with idiopathic scoliosis (182 single curves, 205 double curves). The Stokes formula considers only the lateral dimension. The best predictive formula of the height loss in patients with idiopathic scoliosis is an area for further studies.

In our study, the differences of the pulmonary parameters between the measured and the corrected body height were significant (p<0.001). These differences may influence the interpretation of the spirometry results and classification of the severity of the pulmonary disorders.

## Conclusion and Significance

Corrected body height significantly influences the results of pulmonary parameters measurement. In consequence, it may influence the analysis of the pulmonary status of children with idiopathic scoliosis. The more the Cobb angle increases, the more the differences between the measured and the corrected body height increase, demonstrating the indication for the use of the corrected body height for pulmonary assessment in severe scoliotic curvature.

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# Prevalence of malnutrition and its associated outcomes in pediatric patients with scoliosis undergoing elective posterior spinal fusion or spine growth modulation-a retrospective review

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**Abstract:** Recent attention within pediatric orthopedics focuses on the prevalence and prevention of post-operative complications, including surgical site infections (SSIs). While poor nutrition status has been noted as a risk factor, various definitions have been utilized. The aim of this retrospective chart review was to utilize the Academy of Nutrition and Dietetics (AND) and the American Society for Parenteral and Enteral Nutrition (ASPEN) diagnostic criteria to determine both the prevalence of malnutrition in pediatric patients undergoing spine deformity surgery and its influence on the prevalence of post-operative complications. A total of 2603 patients had a spine procedure between 2012 and 2018. Patients were excluded if they were less than 2 years of age or greater than 18 years of age and/or did not have their spine procedure completed at Children's Wisconsin. Patients who met inclusion criteria and had an irrigation and debridement (I&D) were selected for an I&D group. From the remaining charts, 127 patients were randomly selected for the non-I&D group. Patients in both groups were further divided into well-nourished and malnourished groups. T-tests and chi square tests were used to determine statistical significance. We found that 50% of patients who had an I&D had malnutrition during their clinical course. This is compared with 17% of patients who didn't require an I&D. Additionally, patients requiring multiple surgical interventions, had an increased prevalence of malnutrition. With the recent focus on reducing the prevalence of post-operative complications, the identification and treatment of malnutrition may be helpful in reducing post-operative complications.

**Keywords:** malnutrition, complication, posterior spine fusion, growth modulation

## Introduction

The prevalence of post-operative complications after pediatric spine surgery in high risk populations has been cited up to 8.5% in some populations <sup>1</sup>. The most common complications include SSI, both deep and superficial, repeat surgical interventions, delayed wound healing, post-operative pneumonia and urinary tract infection, prolonged hospitalization and post-operative intubation. These complications lead to increased morbidity and mortality, increased length of stay and subsequent medical and surgical

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interventions. Recent attention in the pediatric spine literature has looked at modification of risk factors to prevent post-operative complications, with a particular focus on SSIs requiring I&D <sup>2</sup>. While the evidence is conflicting, it has been suggested that poor nutrition status is a risk factor associated with the post-operative complications. Various terms have been used in the pediatric orthopedic literature to describe nutrition status including “poor nutrition”, “under nutrition”, and “thinness”, with a lack of uniform criteria to define such terms. The various criteria that have been historically used include laboratory measurements such as: total lymphocyte count, transferrin, pre-albumin, and albumin as well as lesser utilized anthropometric measurements including triceps skin fold, arm circumference and calf circumference <sup>3</sup>. # The body of literature recommends nutrition evaluation of patients prior to undergoing a spine procedure, however, there remains a lack of consensus criteria or uniform guidelines for this evaluation <sup>4</sup>. In 2014, AND and ASPEN published a framework to better define patients with “under nutrition” (Table 1). Their definition of malnutrition is: “an imbalance between nutrient requirements and intake that results in cumulative deficits of energy, protein, or other micronutrients that may negatively affect growth, development and other relevant outcomes” <sup>5</sup>. This is the first paper that has been published citing specific criteria that can be used to make a diagnosis of malnutrition. On literature review, we were unable to find a publication that used the AND/ASPEN diagnostic criteria of malnutrition as a tool to assess potential surgical patients undergoing pediatric spine surgery.

Table 1. Malnutrition Diagnostic Criteria for Patients 2-18 years.[5]

	Mild Malnutrition	Moderate Malnutrition	Severe Malnutrition
<b>BMI for Age Z score</b>	-1 to -1.9	-2 to -2.9	≥ -3
<b>Length/Height for Age Z score</b>	-	-	≥ -3
<b>MUAC Z score (6-60 months)</b>	-1 to 1.9	-2 to 2.9	≥ -3
<b>Weight Loss (&gt;2 years of age)</b>	5% usual body weight	7.5% usual body weight	10% usual body weight
<b>Deceleration in Weight for Length of BMI for Age Z score</b>	Decline of 1 Z score	Decline of 2 Z score	Decline of 3 Z score
<b>Inadequate Nutrient Intake</b>	51-75% estimated energy/protein need	26-50% estimated energy/protein need	<25% estimated energy/protein need

The purpose of this retrospective chart review was to determine the prevalence of malnutrition and its possible effects on post-operative complications amongst pediatric patients with scoliosis who underwent undergoing posterior spinal fusion (PSF) or spine growth modulation. We hypothesize that patients undergoing these procedures, who meet diagnostic criteria for malnutrition at time of surgery will have an increased prevalence of SSI or other adverse post-operative outcomes, as compared to those patients who do not meet these criteria.

Methods

A retrospective chart review was conducted on patients who received a PSF or growth modulation rod placement at our institution from November 1, 2012 through

December 31, 2018. A total of 2603 patients had a spine procedure during this time frame at Children's Wisconsin. Patients were excluded if they were less than 2 years of age or greater than 18 years of age at the time of surgery and/or if they did not have their PSF or growth modulation procedure completed at Children's Wisconsin during the aforementioned time period. To ensure we were able to capture the I&D population, a known indicator of a major post-operative complication, an electronic health record report was run to determine which patients had an I&D procedure/s – of which 16 met inclusion criteria. These patients were included in our I&D study group. Of the remaining charts of patients without an I&D procedure, 143 were randomly selected with 127 patients meeting inclusion criteria.

### *Data Collection*

The following demographic data was obtained via retrospective chart review: age at time of surgery (years), gender (male/female), type of scoliosis, race, ethnicity, type of surgical intervention, primary medical diagnosis (other than scoliosis), pre-operative pre-albumin and/or albumin (if available) and total length of stay for initial surgery. The following anthropometric data was obtained at time of surgical intervention: weight (kg), height (cm), weight for age z-score, and BMI for age z-score. The malnutrition diagnostic criteria met by each patient and overall classification of malnutrition were extrapolated from this data. Data was also collected on the incidence of post-operative complications including development of SSI and/or pressure ulcers, delayed wound healing/dehiscence, and need for repeat surgical intervention.

### *Statistical Analysis*

For the purposes of this study, both the I&D and non-I&D groups were further divided into a well-nourished or malnourished group and were analyzed separately. Patients were categorized as malnourished if they met malnutrition diagnostic criteria at any point during initial surgery or any repeat surgical intervention included in this retrospective review. For purposes of analysis, the type of scoliosis was categorized into idiopathic scoliosis and other scoliosis (neuromuscular, syndromic, thoracogenic, and congenital), the type of spinal procedures patients underwent were grouped into PSF, vertical expandable prosthetic titanium rib (VEPTR), and growing rod modulation and the primary diagnosis was categorized as healthy and neuromuscular condition (spastic quadriplegia, spina bifida, congenital anomalies, genetic syndrome, neuromuscular disease not otherwise specified and muscular dystrophy). With respect to the analysis of complications/adverse outcomes, SSI, delayed wound healing/dehiscence, and/or presence of a pressure ulcer were grouped into one variable. T-test and chi-square tests were completed in order to assess statistical significance between the malnourished and well-nourished groups.

## **Results and Discussion**

### *Demographics – I&D Group*

There were 16 patients included in the I&D group with 8 patients categorized as well-nourished and eight categorized as malnourished. There were no significant

differences between the two groups with respect to age, gender, race, ethnicity, primary diagnosis (other than scoliosis), or weight or BMI for age z-score at initial surgery (Table 2). No patients had idiopathic scoliosis. There was however a slight statistically significant difference between the two groups with respect to type of spinal procedure ( $X^2= 4.67$ ,  $df = 2$  and  $p = 0.097$ ).

Table 2. Comparison of baseline characteristics of patients who underwent an I&D by malnutrition group

Characteristic	Total	No Malnutrition	Malnutrition	P-value
Mean Age $\pm$ SD (N)	16	10.63 $\pm$ 2.9 (8)	10.29 $\pm$ 3.2 (8)	0.522 <sup>t</sup>
<b>Type of Procedure <i>n</i> (%)</b>				
PSF	6	4 (66.7)	2 (33.3)	0.097 <sup>#c</sup>
VEPTR	8	2 (25)	6 (75)	
Growing Rod Modulation	2	2 (100)	0 (0)	

\*Significant with  $p < .05$ , <sup>#</sup>significant with  $p < .1$ , <sup>t</sup>T-test, <sup>c</sup> Chi Square Test

*Demographics – Non- I&D Group*

There were 127 patients include in the non-I&D group with 106 patients categorized as well-nourished and 21 patients categorized as malnourished. There were no significant differences between the two groups with respect to age, gender, ethnicity, type of scoliosis, and primary diagnosis (other than scoliosis) (Table 3). The groups did however have statistically significant differences with respect to race ( $X^2= 8.48$ ,  $df = 3$  and  $p = 0.037$ ), type of procedure ( $X^2= 5.80$ ,  $df = 2$  and  $p = 0.055$ ), and weight and BMI for age z-score at initial surgery. With respect to weight at initial surgery, the well-nourished group ( $M=54.19$ ,  $SD= 18.29$ ) had a significantly higher weight than the malnourished group ( $M=41.40$ ,  $SD = 16.17$ ),  $t(125) = 2.98$ ,  $p<0.001$ . The well-nourished group ( $M=0.36$ ,  $SD= 1.38$ ) also had a significantly higher BMI for age z-score at initial surgery than the malnourished group ( $M=-0.94$ ,  $SD = 1.12$ ),  $t(119) = 4.02$ ,  $p<0.001$ .

Table 3. Comparison of baseline characteristics of patients who did not undergo an I&D by malnutrition group

Characteristic	Total	No Malnutrition	Malnutrition	P-value
Mean Age $\pm$ SD (N)	127	13.63 $\pm$ 2.8 (106)	13.48 $\pm$ 4.1 (21)	0.832 <sup>t</sup>
Type of Scoliosis <i>n</i> (%)				
Idiopathic	85	73 (86)	12 (14)	0.297 <sup>c</sup>
Other	42	33 (79)	9 (21)	
Type of Procedure <i>n</i> (%)				
PSF	114	98 (86)	16 (14)	0.055 <sup>#c</sup>
VEPTR	9	5 (56)	4 (44)	
Growing Rod Modulation	4	3 (75)	1 (25)	

\*Significant with  $p < .05$ , <sup>#</sup>significant with  $p < .1$ , <sup>t</sup>T-test, <sup>c</sup> Chi Square Test

*Adverse Outcomes –I&D Group*

Of the patients in the I&D group, two patients (13%) met malnutrition criteria at their initial surgery with an additional six patients developing malnutrition at some point in their clinical course. As such, a total of 50% of patients requiring an I&D met malnutrition diagnostic criteria at some point during their clinical course. Of those that met malnutrition criteria, 25% maintained a diagnosis of malnutrition throughout their clinical course. Additionally, it was noted that of the 8 patients who developed malnutrition, 75% of them underwent a VEPTR procedure ( $X^2 = 4.67$ ,  $df = 2$  and  $p = 0.097$ ). With respect to adverse outcomes, all patients in this group were considered to have at least one complication, as all patients required an I&D, with 88% of patients exhibiting more than one complication at any point during their clinical course. No significant differences were observed between the well-nourished and malnourished groups with respect to adverse outcomes and total length of stay.

*Adverse Outcomes – Non- I&D Group*

In the non I&D group, 19 patients (15%) met criteria for malnutrition at the time of initial surgery. While not all patients required lengthenings, of the 10 patients that did, 50% of them developed malnutrition at some point during their clinical course with 80% of them maintaining a malnutrition diagnosis throughout their clinical course. With respect to adverse outcomes, 13% of patients experienced a complication at some point in their clinical course. Of the patients that had an adverse outcome, 25% had greater than one complication throughout their clinical course. No significant differences were observed between the well-nourished and malnutrition group with respect to adverse outcomes and total length of stay.

*Pre-Albumin and Albumin*

Sixty-three patients in our sample had a pre-albumin and/or albumin level drawn prior to surgery, as this has historically been practice in pediatric orthopedics to screen for malnutrition. Of those laboratory values, 95% were noted to be within normal limits. Of the three low laboratory values, only one occurred in a patient who also had a malnutrition diagnosis. Of the 60 patients who had normal labs, 11 (18%) had a malnutrition diagnosis at any point during their clinical course.

This study aimed to retrospectively determine the prevalence of malnutrition in pediatric scoliosis patients who underwent a PSF or growth modulation and to determine if those with malnutrition had an increased prevalence of adverse outcomes. This study was able to show that patients who required multiple surgical interventions had a higher prevalence of malnutrition. Our data also indicates that those that develop malnutrition are more likely to continue to be malnourished throughout subsequent procedures. The major limitations of this study were a small sample size, low prevalence of complications at our institution, and lack of a completely randomized sample. As the I&D population was not randomly selected, we were unable to compare the I&D population with the non-I&D population to further assess the influence of malnutrition. Despite these limitations, this study demonstrates that while patients may not meet malnutrition criteria when they initially present for spine surgery, as they undergo subsequent procedures they become at risk for and are more likely to develop malnutrition. As such, we encourage orthopedic teams to preoperatively evaluate patients for malnutrition prior to all spine deformity

procedures, especially in patients who will need to undergo multiple procedures such as with VEPTR lengthenings and growth modulation. If a patient is at risk of or meets criteria for malnutrition, consider postponing surgery and implementing a nutrition intervention or involving a Registered Dietitian in the patient's care if possible. More research is needed on this topic to better understand the role of malnutrition and/or pre-operative improvement or resolution of malnutrition and its impact on post-operative outcomes. Future work focusing on a larger sample size, with randomized groups as well as data from other institutions would prove beneficial to the breadth of this work. Furthermore, more research is needed to determine the best method for orthopedic teams to use when screening patients for malnutrition risk.

## Conclusion and Significance

This study showed that patients undergoing multiple surgical procedures, such as with growing rod technology, had a higher prevalence of malnutrition. With the breadth of the pediatric orthopedic community focusing on reducing the prevalence of SSIs, focusing on the identification and treatment of malnutrition may be a helpful tool in reducing post-operative complications, specifically SSIs requiring I&D.

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# Is there any difference in pulmonary testing parameters due to spirometry reference values? A study in adolescents with idiopathic scoliosis

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**Abstract:** The Global Lung Function Initiative (GLI 2012) presented multi-ethnic spirometry reference values that are recommended to be used instead previous Zapletal's reference values. The study aimed to compare the values of the pulmonary parameters calculated according to the Zapletal's versus the GLI 2012 reference values in adolescents with idiopathic scoliosis. Preoperative pulmonary testing and radiographic evaluation were performed in 39 adolescents (29 females, 10 males) aged 12-17 years. The thoracic Cobb angle ranged 50°-104°. Forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) were measured. The percentages of predicted values of FVC (%FVC) and the FEV1 (%FEV1) were calculated according to the Zapletal's reference values and to the GLI 2012 reference values. The subgroup analysis was performed for the subjects with Cobb curve 50°-74° (N=26) versus the subjects with Cobb curve 75°-104° (N=13). Mean %FVC was significantly higher using the Zapletal's reference values 86.1%±16.4 versus 84.6%±15.6 using the GLI 2012 reference values, p=0.0116. Mean %FEV1 was significantly higher using the Zapletal's reference values 84.5% ±18.2 versus 80.0% ±16.3 using GLI 2012 reference values, p=0.000001. The subgroup analysis revealed significant difference of %FVC in moderate (p=0.033974) and no difference in severe curves (p=0.1993). The %FEV1 differences were significant in both moderate (p=0.000011) and severe curves (p=0.0334). The study demonstrated that a significant difference might be observed in the spirometry parameters due to the applied reference values. These differences might be taken into account during the spirometry examination interpretation.

**Keywords:** GLI 2012, Zapletal reference values, idiopathic scoliosis, pulmonary function test

## Introduction

In 2012 Global Lung Function Initiative (GLI 2012) presented multi-ethnic spirometry reference values for age range 3-95 years.[1] The European Respiratory Society (ERS) and other international respiratory societies recommended the GLI 2012 to be used instead of the previously used, e.g., Zapletal's reference values. [2-4]

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The study aimed to compare the values of the pulmonary parameters calculated according to the Zapletals' versus the GLI 2012 reference values in adolescents with idiopathic scoliosis.

## **Methods**

The study consisted of 39 adolescents (29 females and 10 males) aged 12-17 years with diagnosed idiopathic scoliosis. Preoperative pulmonary testing and radiographic evaluation were performed in all patients prior to the surgery.

Radiological measurements were performed on the standard anteroposterior radiographs of the spine. Thoracic Cobb angle value was measured based on the Cobb method.[5]

The spirometry examination was performed in a sitting position using a turbine spirometer. As parameters that provide the lung volume and flow assessment, Forced Vital Capacity (FVC) and Forced Expiratory Volume 1 second (FEV1) were chosen. Patients performed spirometry examination three times and the single best effort was analyzed. The spirometer software automatically calculated the percentage of the predicted values of FVC (%FVC) and FEV1 (%FEV1) according to the Zapletals' reference values. Then, the values of %FVC and %FEV1 were calculated according to the GLI 2012 reference values using the Global Lung Function Initiative software for calculating predicted values for individuals (available to download on the ERS website).

Based on the thoracic Cobb angle's value, patients were divided into two subgroups: subgroup I. moderate scoliosis with the curve magnitude within the 50°-74° (N=26); subgroup II. severe scoliosis with the curve magnitude within 75°-104° (N=13).

The mean value, standard deviation and range of the parameters were calculated. Normal data distribution was analyzed with Shapiro-Wilk test. The Student's-t Test was used to determine the significances between pulmonary parameters (%FVC and %FEV1) calculated according to the Zapletals' and GLI 2012 references values. The analysis was performed with Statistica Software (TIBCO Software Inc.).

## **Results and Discussion**

Mean thoracic Cobb angle was  $69.8^{\circ} \pm 12.4$  (range 50°-104°). Mean FVC was  $3.25L \pm 0.84$  (range 1.58-5.47). Mean FEV1 was  $2.67L \pm 0.68$  (range 1.28-4.04).

The %FVC was significantly higher using the Zapletals' reference values  $86.1\% \pm 16.4$  (range 55-125) versus  $84.6\% \pm 15.6$  (range 52.9-116.3) when using the GLI 2012 reference values ( $p=0.0116$ ). Mean %FEV1 was significantly higher using the Zapletals' reference values  $84.5\% \pm 18.2$  (range 41-123) versus  $80.0\% \pm 16.3$  (range 40.2-107.9) when using GLI 2012 reference values ( $p=0.000001$ ). The subgroups results are presented in Table 1.



Table 1. Results of the pulmonary parameters

Parameter	Thoracic Cobb angle [°]	Zapletals' reference values	GLI 2012 reference values	p-value
%FVC	50-104	86.1 ±16.4 (55-125)	84.6 ± 15.6 (52.9-116.3)	0.0116*
	50-74	87.9 ± 13.7 (62-116)	86.3 ± 13.0 (62.7-114)	0.033974*
	75-104	82.5 ± 20.9 (55-125)	81.3 ± 20.0 (52.9-116.3)	0.1993
%FEV1	50-104	84.5% ±18.2 (41-123)	80.0% ±16.3 (40.2-107.9)	0.000001*
	50-74	86.5 ± 16.0 (41-118)	82.0 ± 14.3 (40.2-104.7)	0.000011*
	75-104	80.61 ± 22.1 (51-123)	75.9 ± 19.8 (46.9-107.9)	0.0334*

%FVC-percentage of predicted value for FVC; %FEV1- percentage of predicted value for FEV1. All values are presented as mean, standard deviation, minimum and maximum in the brackets.\*- value statistically significant

The reference values proposed by Zapletal were based on limited group of 111 children (boys and girls) aged 6-17 years old. Furthermore, the equations considered only childrens' gender and standing body height.[4] On the contrary, the GLI 2012 reference values are based on a large and representative sample of 97 759 healthy nonsmokers aged 2.5-95 years old (15 264 girls and 15 601 boys age 2.5-18years old) and provide the equations to calculate the percentages of the pulmonary parameters' predicted values according to the patients' gender, standing body height and ethnic group for age span 2.5 to 95 years old.[1,2]

The results of our study have shown the significant differences between percentages of the predicted values of FVC and FEV1 in adolescents with idiopathic scoliosis calculated according to the Zapletals' versus GLI 2012 references values. Also, previously conducted studies revealed that change from the Zapletals' to the GLI 2012 reference values does impact the spirometry results interpretation in children and adolescents with asthma, cystic fibrosis, dyspnea, cough, and in healthy subjects.[2,6-9]

Conclusion and Significance

The study demonstrated that a significant difference might be observed in the spirometry parameters due to the applied reference values. These differences might be taken into account during the spirometry exam interpretation. Further, studies are recommended to assess the clinical importance of these findings

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## Chapter 12

# Abstracts for Genetics, Etiology, Growth, and Metabolism

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## Global DNA methylation level in females with idiopathic scoliosis

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**Introduction:** Studies on the etiology of idiopathic scoliosis (IS) suggest that it is a multifactorial disease with a significant genetic background, modulated by environmental factors. The identification of the epigenetic factors which are the linkage between genome and environment is needed. One of the most important epigenetic modifications is the DNA methylation. DNA methylation, which is modulated by both genetic factors and environmental exposures, may offer a unique opportunity to discover novel biomarkers of scoliosis phenotypes. There is limited knowledge about importance of the gDNA methylation in IS.

**Objective:** The aim of this study was to evaluate of the level of global gDNA methylation in patients with IS and in healthy controls.

**Methods:** 79 girls with IS were included into study group. The Cobb angle and the Risser sign were established. The patients with IS were divided into two subgroups according to disease severity: moderate IS N= 52 (patients with Risser sign 4 and 5 and Cobb angle 10-30°) and patients with severe IS N=27 (Cobb angle >50°). 40 healthy females were included into control group. In this group the clinical examination was performed to exclude IS and other spine disorders. Blood samples were obtained from each person and gDNA was isolated. The quantitative analysis of the gDNA was performed with MethylFlash Global DNA Methylation 5-mc ELISA Easy Kit (Colorimetric; EpiGentek, USA) according to manufacturer's protocol. The percentage of methylated cytosines was calculated and established as a level of gDNA methylation.

**Results and Discussion:** The level of the gDNA methylation in IS group was 1.61%±1.21% (0.12%-5.98%) and in the control group was 1.97%±1.32% (0.17%-5.47%), p=0.113. There was no significant difference in the level of the gDNA methylation between patients with moderate 1.59%±1.07% (0.12%-3.94%) versus severe 1.66%±1.46% (0.16%-5.98%) form of IS, p=0.891. The difference in the global gDNA methylation between patients with idiopathic scoliosis and control group was not significant.

**Conclusions and Significance:** The global gDNA methylation level revealed no association with the severity of the disease. It is possible that more gene specific factors play role in development of IS and the global gDNA methylation seems of limited utility.

## The mechanobiology of differential growth in Adolescent Idiopathic Scoliosis

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**Introduction:** Adolescent Idiopathic Scoliosis (AIS) is a multifactorial disorder that has been linked to genetic, hormonal, neurological, microbial and environmental cues. Eventually, however, AIS is a mechanical deformation of the spine, so an adequate theory of etiopathogenesis must provide an explanation for this and address the forces involved.

**Objective:** In previous research with a physical model of the spine we showed that restrained differential growth, a mismatch of growth in mutually attached tissues, can result in the typical sequence of three-dimensional deformations seen in AIS.[1] Here we aim to identify the mechanobiological principles that may underlie this phenomenon and explain the deformities observed.

**Methods:** We performed a literature study in Pubmed using the keywords growth, spine, tensegrity, muscle strength, vertebral body, growth plate, Hueter-Volkman Law, intervertebral disc height, ligament, notochordal cells, and osmosis. Relevant information was gathered and combined for a comprehensive theory of etiopathogenesis for AIS.

**Results and Discussion:** The human body is a *tensegrity-like* structure, in which muscles, ligaments and fasciae stabilize the skeleton. As the child grows, bone and cartilage elongate the muscles, ligaments and fasciae and induce their remodeling and growth. Considering the literature, we suggest the following scenario for the etiopathogenesis of AIS. During the growth spurt, there is a delay in muscular maturation, resulting in lowered prestress and decreased stability of the skeleton. According to *Hueter-Volkman*, reduced axial compression enhances the growth of bones, which is indeed observed in AIS patients. Decreased spinal compression further results in lower vertebral bone density and increased disc height. Reduced dynamic loading also preserves the notochordal cells in the nucleus pulposus, which stimulates the production of proteoglycans and the assembly of the osmotic extracellular matrix. This intradiscal pressure increases intervertebral disc height to its limits, rendering the longitudinal ligaments and the annulus fibrosus under excessive tension (Figure 1). Under these conditions, spinal ligaments cannot remodel and therefore not grow with the intervertebral discs. The enhanced intradiscal pressure and locked ligamental remodeling embody the differential growth of the spine that results in scoliotic bending and rotation.

**Conclusion and Significance:** AIS has been related to many physiological cues, yet the deformations observed remain essentially unexplained. The suggested differential growth mechanism fits well with the timing and speed of scoliotic deformations during the adolescent growth spurt. The identification of increased intradiscal pressure as the driving force of scoliotic deformities may be helpful to design prevention and treatment strategies for AIS.

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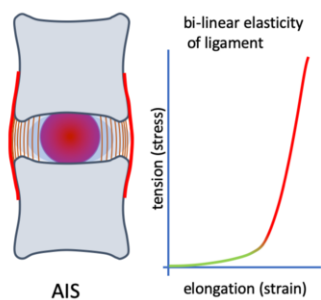


Figure 1: High intradiscal (osmotic) pressure results in high tension in the anterior and posterior longitudinal ligaments, which are thereby inhibited to remodel and grow.

## A systematic review update of a single-gene etiology theory for Adolescent Idiopathic Scoliosis

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**Introduction:** Adolescent Idiopathic Scoliosis (AIS), a common spinal condition, affects 2-4% of the population and occurs in otherwise completely healthy adolescents. The underlying cause of the disease is not fully known. Multiple disciplines to date have sought to elucidate the etiology of AIS without conclusion. While a genetic or familial component is likely based on known common family history data, researchers continues to look for a single-gene etiology. A focus on a better understanding of the multiple factors that may be involved, including inherent susceptibility, growth, biomechanics of AIS, bone health and other related issues— instead of trying to find a single genetic ‘silver bullet’ etiology— may be useful.

**Objective:** The objective of this study is to critically evaluate more current reports on a single-gene cause of AIS through a systematic review and strength-of-study analysis of genetic and genome-wide association studies. Modern meta-analyses protocols of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were utilized.

**Methods:** PRISMA flow diagram guidelines were followed. PubMed was searched for: AIS, scoliotic, spinal curve, genetic, gene, etiology, polymorphisms. Articles were assessed for risk of bias using a scoring system. The remaining articles also underwent level of evidence grading via Oxford Centre for Evidence-Based Medicine criteria. The scores from the assessments factor toward strength of a study in providing a positive or negative association to a single-gene etiology.

**Results and Discussion:** Initially, 36 relevant articles were identified. After following risk-of-bias inclusion criteria, 8 articles were studied in the qualitative analysis. Of the 8 studies analyzed, 3 were in favor of a single genetic link for AIS, whereas the other 5 studies were against a single-gene etiology. Based on the literature analyzed, there is moderate evidence with a low risk-of-bias that does not clearly support a single-gene theory for the etiology of AIS.

**Conclusion and Significance:** The etiology of AIS is likely multifactorial with complex interplay between various factors. Therefore, solely relying on a single genetic cause for AIS simplifies critical thinking and inhibits study of a complete picture that explains its likely multifactorial nature and blocks out objective evaluation of the multitude of involved influences. A synthesis of factors such as inherent susceptibility, growth, biomechanics, bone health and other factors, including genetics, will aid in creating a complete picture that explains the likely multifactorial nature of AIS. An understanding of the contributing multiple factors can aid in defining the condition and in developing innovative, non-invasive, and personalized treatments plans for AIS patients.

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# Abnormal expression of *PAX3* in paravertebral muscles of patients with Adolescent Idiopathic Scoliosis

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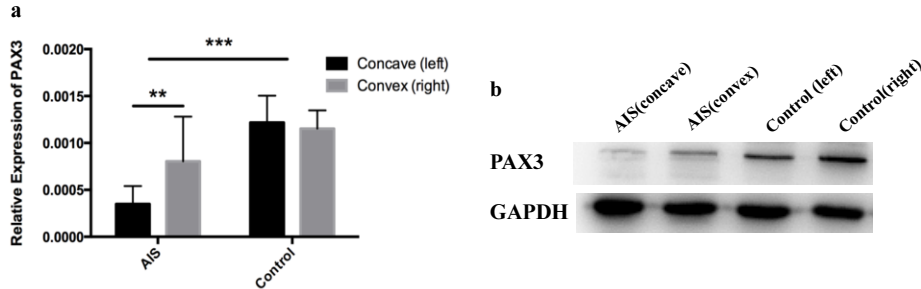
**Introduction:** The abnormality of paravertebral muscle has been widely proposed to explain the etiology of adolescent idiopathic scoliosis (AIS). Our previous genome-wide association studies have identified several new susceptibility locus for ASI in *PAX3* gene, which is essential for the development of muscles.

**Objective:** The study is aimed to investigate the expression of *PAX3* in bilateral paravertebral muscles in AIS and controls, and to further clarify its association with the paravertebral muscle volume and curve severity.

**Methods:** Ten AIS patients and 10 age-matched controls with lumbar disc herniation were included. Bilateral paravertebral muscles were obtained at the apical vertebral level for patients and at the L5 level for controls. The concave and convex expression of *PAX3* was compared between the two groups. The AIS patients were evaluated with magnetic resonance imaging (MRI) scan of the spine at the apex. The muscle volume of apical paravertebral muscles were measured and compared between concave and convex side. Correlation between concave/convex *PAX3* expression ratio and concave/convex muscle volume ratio were analyzed.

**Results and Discussion:** AIS patients were found to have significantly lower *PAX3* expression than controls ( $p<0.001$ ). Moreover, *PAX3* expression on the concave side was lower than that on the convex side in AIS ( $p=0.003$ ). The muscle volume on the concave side was smaller than convex side as well ( $p=0.001$ ). The *PAX3* expression ratio was significantly correlated with the muscle volume ratio ( $r=0.745$ ,  $p=0.013$ ), however, there was no significant correlation between the *PAX3* expression ratio and Cobb angle ( $r=0.284$ ,  $p=0.427$ ).

**Conclusion and Significance:** The *PAX3* muscle expression and paravertebral muscle volume were asymmetric in AIS patients, and the expression ratio was positively related with the muscle volume ratio. These findings suggest *PAX3* may have functional role in the development of AIS via regulating development of paravertebral muscle.



## LBX1 may play a role in the development of AIS via regulating the proliferation and differentiation of myosatellite cells

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**Introduction:** LBX1 is a susceptible gene involved in the etiology of adolescent idiopathic scoliosis (AIS) in different populations. In our earlier study, a functional variant in the promoter region of LBX1 was confirmed to regulate the expression of LBX1 in the paraspinal muscles of AIS. Interestingly, AIS patients were reported to have abnormally distribution of Type I fiber in the bilateral paraspinal muscle.

**Objective:** In this study, we aimed to investigate the influence of LBX1 on the bioactivity of myosatellite cells isolated from AIS patients.

**Methods:** Bilateral paraspinal muscles were collected from the 20 AIS patients and 10 age-matched congenital scoliosis (CS) patients during surgery. All the patients had major thoracic curve with the curve magnitude matched between the two groups. Immunohistochemical staining was performed to determine the ratio of type I fiber to type II fiber for each sample. The tissue expression of LBX1 was evaluated by qPCR to determine its relationship with the proportion of Type I fiber. Myosatellite cells were then isolated from the paraspinal muscles and then purified accordingly. 10 cases of AIS cells were randomly selected, with 5 cases transfected by LBX1 lentivirus and with the other 5 cases transfected by empty vector. All the cells were cultured until the fusion of myotube was observed. Cell proliferation assays were performed with a Cell Counting Kit-8. Cell differentiation was assessed using MF20 (myosin heavy chain) immunostaining. Cell viability was then compared between AIS and CS and between lentivirus-transfected group and blank group.

**Results and Discussion:** Immunohistochemical staining of the tissue sample showed that there was remarkably decreased proportion of Type I fiber in AIS as compared with CS. LBX1 expression was significantly correlated with proportion of Type I fibre. Myosatellite cells isolated from AIS presented lower viability than those of CS. In the lentivirus-transfected group, activated myosatellite cells were found to have significantly inhibited proliferation rate. Moreover, remarkably decreased number of Type I fiber was observed after the silencing of LBX1.

**Conclusion and Significance:** LBX1 may be involved in the etiology of AIS through regulation of myosatellite cells in the paraspinal muscles. Disproportion of Type I fibre in paraspinal muscle may play a role in the occurrence of AIS. Further microarray analysis is warranted to determine the downstream pathway of LBX1 that contributes to the myogenesis of AIS.

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## ***LONPI* is associated with the incidence of idiopathic scoliosis possibly via defective mitochondrial function**

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**Introduction:** AIS patients were featured by low body mass index, abnormal lipid metabolism and weak muscle strength. Mutations in mitochondrial function related genes have been reported to lead to various phenotypes including scoliosis. To date, there was a lack of study investigating the energy metabolism and mitochondrial function in AIS patients.

**Objective:** This study aimed to determine whether mitochondrial dysfunction is involved in the development of AIS.

**Methods:** Paraspinal muscles were collected from the 20 IS patients and 20 patients without spinal deformity during surgery. Cytochrome-c oxidase (COX) enzyme activity of mitochondria was investigated for the patients and the controls by histochemistry of the muscles samples. Total RNA was extracted for the expression analysis of *LONPI* via qPCR. Exons of *LONPI* were sequenced in 96 patients to identify novel mutations, which were then replicated in 1000 AIS and 1000 healthy controls. *LONPI* knock-out mouse model was then established.

**Results and Discussion:** AIS patients were found to have remarkably COX deficiency as compared with the controls. *LONPI* was found significantly down-expressed in the IS patients as compared with the controls ( $0.00025 \pm 0.00017$  vs.  $0.00047 \pm 0.00032$ ,  $p < 0.01$ ). Exon sequencing showed a novel missense variant (c.70C>G) in 3 patients, which was then successfully replicated in the independent cohort ( $0.018$  vs.  $0.008$ ,  $p = 0.04$ ). Homozygous *LONPI* knock-out mice showed scoliotic curve in the thoracic region.

**Conclusion and Significance:** Mitochondrial dysfunction was observed in the paraspinal muscles of AIS patients. Novel mutation of *LONPI* is associated with the development of AIS. Disruption of *LONPI* in mice could lead to remarkable scoliotic curve. Mitochondrial dysfunction may play an important role in the etiology of AIS.

## Methylation level of the regulatory regions of the estrogen receptor type 1 gene in paravertebral muscles of girls with idiopathic scoliosis

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**Introduction:** It is postulated that estrogens may be related to development and progression of idiopathic scoliosis (IS). Estrogen receptors mediate effects of estrogens. Expression of estrogen receptor 1 (ESR1) has been confirmed in muscle tissue. The tissue specific expression of the *ESR1* may be regulated due to methylation of the T-DMRs region of the gene. There are studies describing difference in muscles fibers between the convex and the concave side of the curvature in IS.

**Objective:** The aim of the study was to analyze the methylation level within the regulatory regions of the of the *ESR1* which are present in the back muscle tissue of patients with IS.

**Methods:** The study involved 31 girls operated due to IS. The patients were divided into severe or very severe idiopathic scoliosis according to Cobb angle  $\leq 75^\circ$  and  $>75^\circ$ . Muscles samples were taken during surgical procedure from deep paravertebral muscles both on the convex and the concave side of the curve and one sample was taken from back superficial muscles. Two *ESR1* regulatory fragments were selected T-DMR1 with four and T-DMR2 with eight CpG dinucleotides. The methylation level was assessed in 2 steps: 1) conversion of genomic DNA, based on deamination with sodium bisulfite of unmethylated cytosine to uracil; 2) PCR reaction combined with quantitative methylation analysis using designed primers and pyrosequencing reaction.

**Results and Discussion:** The level of methylation was significantly higher in the superficial muscles than in the deep paravertebral muscles in three of four analyzed T-DMR1 CpGs ( $p < 0.03$ ) and in seven T-DMR2 CpGs ( $p < 0.03$ ). No difference was found in T-DMR1 and T-DMR2 methylation level between patients with severe vs. very severe IS at the convex and concave side of the curvature. However, the mean of the methylation level measured at the concave and convex side was significantly higher in three CpGs of T-DMR2 region in case of patients with severe vs. very severe IS ( $p < 0.05$ ).

**Conclusions and Significance:** The methylation level of the regulatory regions of the *ESR1* is specific to the muscle tissue localization. The difference in T-DMR2 CpGs methylation level may be associated with the IS severity.

## Ovine model of congenital chest wall and spine deformity with alterations of respiratory mechanics: follow-up from birth to three months

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**Introduction:** The adverse effects of spinal and thoracic deformities (STD) on respiratory mechanics have been suggested in the literature. However, most animal studies evaluated respiratory mechanics in a STD model created postnatally.

**Objective:** We developed an ovine model of spinal and thoracic deformity induced surgically in utero, in order to assess its consequences on lung mechanics and development.

**Methods:** Experimental animal study: A STD was induced in utero at 70-75 days of gestation in 14 ovine fetuses by resection of the 7th and 8th left ribs. Each untouched twin fetus was taken as control. Respiratory mechanics was studied in the first week of life and at one, two and three months postnatally using a Servo-I ventilator (Getinge AB, Sweden). In addition, post-mortem respiratory mechanics and lung histomorphometry were also assessed at three months. Mann-Whitney U tests were performed to evaluate statistical significance.

**Results and discussion:** Eight out of 14 STD lambs (57%) and 14 control lambs survived the postnatal period. The causes of death included abortion (n = 3), prematurity (n = 1), respiratory insufficiency at birth (n = 1) and stillbirth (n = 1). One severe (51° Cobb angle) and 5 mild deformities were induced (two with 13°, two with 10° and one with 7.5° Cobb angle). The inspiratory capacity was decreased at birth in STD lambs (32 vs. 35 ml/kg in controls,  $p = 0.02$ ), as well as the static respiratory system compliance (2.0 vs. 2.5 ml/cmH<sub>2</sub>O/kg,  $p = 0.005$ ). No significant differences in respiratory mechanics were seen thereafter (Table). Finally, the alveolar surface area was significantly ( $p < 0.05$ ) decreased in the five STD compared to the four control lambs studied at 3 months of life.

**Conclusion and significance:** This is the 1<sup>st</sup> study that evaluates the effects of a STD induced in utero on respiratory mechanics in an ovine model from birth to three months of age. This is also the first study to show significant alterations in lung histomorphometry at three months of age in STD lambs. Although the alterations in respiratory mechanics present at birth in STD lambs resolved during development, this may be related to the challenge in inducing severe deformities in this model. Our ovine model allows a closer replication of congenital spine and chest deformities. It does not however generate protracted alterations in respiratory function caused by severe deformities.

Table: Summary data of measurements of respiratory mechanics in vivo from birth to 3 months of life in an ovine model after the resection of the 7<sup>th</sup> and 8<sup>th</sup> left ribs to induce a spinal and thoracic deformities

		Inspiratory Capacity (mL/kg)	P-values	Dynamic Compliance (mL/cmH2O/kg)	P-values	Static Compliance (mL/cmH2O/kg)	P-values
First Day of life	CTRL (n=14)	32	<b>0.02</b>	1.8	<b>0.005</b>	2.5	<b>0.005</b>
	STD (n=8)	35		1.4		2	
1 month	CTRL (n=14)	28	<b>0.04</b>	1.3	0.1	1.8	0.3
	STD (n=8)	24		1.2		1.6	
2 months	CTRL (n=14)	21	0.2	0.8	0.1	1	0.7
	STD (n=8)	19		0.7		1	
3 months	CTRL (n=14)	19	0.2	0.6	0.2	0.8	0.2
	STD (n=8)	16		0.6		0.8	

## Anterior vertebral body growth modulation for idiopathic scoliosis: early, mid-term and late complications

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**Introduction:** Anterior vertebral body growth modulation (AVBGM) is an emerging option with evolving indications for the treatment of idiopathic scoliosis (IS). However, the spectrum and impact of the potential complications are not yet well defined.

**Objective:** We aim to show that the complications of AVBGM for idiopathic scoliosis differ from the classic posterior fusion and that they can be clustered as early, mid-term, and late-term.

**Methods:** A prospective cohort of sixty-two patients (mean age 11.8±1.3y.old) operated for IS with AVBGM between December 2013 and October 2017; all had 2 to 5-year follow-up (mean 39±9 mo, range=23-58mo). Prospective analysis of pre- and postoperative data included patient specific parameters, radiographic measurements and recording complications and their respective management. Statistical analysis used descriptive measures and independent t-tests.

**Results and Discussion:** Tether breakage was identified in 22 patients (36%). Besides, 12 other complications were noted in 12 patients (Table). Three Pulmonary complications and 2 CSF leaks were seen early (median=18.0±30.0days and median=6.5±4.9 days, respectively). Three overcorrections (requiring tether removal) and 1 insufficient correction for a 75°-large curve (requiring PSF) were seen at mid-term (median=19.0±7.5 months and 18.0 months, respectively). At long-term, we identified 22 tether breakages, 2 coronal decompensations, and 1 lumbar curve progression (median=32.0±6.9 months, median=32.0±6.9 months, and median=29.0±20.0 months, respectively). Reoperation rate was 13% (8/62). Furthermore, instrumenting closer to the vertebrae touched by the CSVL seems to correlate significantly with lower overall complications (p=0.017) and a tendency towards lower tether breakage (p=0.084).

**Conclusion and Significance:** Complications of AVBGM differ from those of classic posterior fusion in nature and timing. Pulmonary complications and CSF leak may be seen in the first 90 days. Over- or under-correction likely happen within 2 years as growth is maximal during this period. Tether breakage, coronal decompensation and lumbar curve progression are rather encountered from 2 to 5 years. Instrumenting distally closer to the vertebrae touched by the CSVL seems to add a protective effect. The overall complication rate following AVBGM is low with returns to OR occurring in the mid- to late- post-operative period.

Complications of Anterior Vertebral Body Tethering in 62 Patients with Idiopathic Scoliosis		
Early (0 - 90 days)	Mid-term (3 months - 2 years)	Long-term (2 - 5 years)
Pulmonary complications (Hemothorax, pneumothorax) (n=3)	Overcorrection (n = 3)	Tether breakage (With or without significant thoracic curve progression) (n = 22)
Cerebrospinal fluid leak (n=2)	Insufficient correction (n = 1)	Coronal imbalance (n = 2)
		Progression of lumbar curve (n = 1)



## A composite model to predict curve severity of Adolescent Idiopathic Scoliosis (AIS) - a 6-years longitudinal study beyond skeletal maturity

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**Introduction:** Adolescent Idiopathic Scoliosis (AIS) is a rotational spinal deformity occurring predominantly in 10-13 years old girls with a global prevalence of 1-4%. Severe spinal deformity in AIS is associated with functional morbidities, cardiopulmonary compromise, early spinal degenerative changes and psychosocial disturbance. With unclear etiopathogenesis of AIS, the search for risk evaluation of curve severity at early stage for timely intervention is an important clinical question that has yet to be solved. Considering the clinical heterogeneity and the involvement of multifaceted pathomechanisms of AIS, it is more logical to develop composite models with clinically applicable and interpretable quantitative factors for predicting the probability of disease progression. Together, our study demonstrates a new composite model that could potentially predict curve progression in patients diagnosed with AIS.

**Objective:** To identify key clinical and serological parameters which are closely related to curve severity of AIS, and to established a composite model able to predict curve progression to severe deformity (Cobb angle  $>40^\circ$ ).

**Methods:** AIS girls (N=120) were recruited from our Scoliosis Research Clinic at their first clinical visit, followed by blood taking and measurement of anthropometry and curve severity. The AIS subjects were followed up by clinically every 6 months for 6 years. Severe AIS was defined as Cobb angle  $>40^\circ$ . Serum CTX/PINP and plasma miRNA level were determined.

**Results and Discussion:** Twenty-seven subjects were defined as Severe AIS at the end of 6 years. Severe AIS had higher serum level of PINP and lower plasma level of miR-145 significantly compared to AIS with Cobb angle  $<40^\circ$ . Plasma miR-145 level showed negative correlation with Cobb angle ( $p=0.002$ ). Predictive model composing of clinical anthropometric parameters, serum PINP and plasma miR-145 showed outstanding power to predict curve severity with  $R^2$  of 0.575, sensitivity of 91%, specificity of 79% and hazard ratio of 27.6.

**Conclusion and Significance:** We constructed a logistical regression equations not only with outstanding power of prediction in curve severity, but also provided a new quantitative system to clinical with a clear cut-off reference. Subjected to further longitudinal multi-centre validation with the younger AIS patients from different ethnic groups, the composite model could help inform timely clinical decisions on bracing treatment for the potential progressive group.

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# Chapter 13

## Abstracts for Spine Biomechanics and Numerical Modeling

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## 3D printed EBDB for juvenile scoliosis: experience with its design, materials and process

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**Introduction:** 3D printing technology has been gradually incorporated into the orthotic industry, where several case serial studies with different styles of braces, including diverse materials, thickness, and surface lattices, were reported in the literature. Up until now there has been no standard for a rapid prototyping process in manufacturing the 3D printed brace with respect to its design, biomechanical properties, and procedures. Additionally, there is a lack of knowledge of how to fit the 3D printed brace.

**Objective:** The purposes of this study were: 1) to find out a reliable and effective workflow in manufacturing of 3D printed Elongation Bending De-Rotation Brace (EBDB) based upon a rapid prototyping industrial standard, including design, material properties, and processing; 2) to provide feedback from fitting of the brace; 3) to evaluate spinal alignment changes in X-ray.

**Methods:** One girl diagnosed with juvenile idiopathic scoliosis at age of 9 years and 8 months was studied. The Torso Measurement Frame (TMF) was used to correct her abnormal trunk and a hand-held scanner recorded the 3D torso digitally. The EBDB was designed using CAD and analyzed structurally using FEA. To define an efficient manufacturing workflow, the CAD model was imported in GrabCAD® (Stratsys, Eden Prairie, MN) and the most efficient print direction and method was determined in terms of minimal print time, printing cost and printer type. The brace was printed on a Stratsys F370 using ABS material and the FDM (Fused Deposition Modeling) method.

**Results and Discussion:** The FEA determined that the minimum thickness of the brace should be 2 mm in order to maintain a standard structural factor of safety twice that of material failure strength. Analysis indicated that 20 hours would be required to print the brace in a vertical orientation. Even though FDM is not the fastest printing method, it is the least expensive method. The ABS was chosen because this material is among the strongest, stiffest and highest impact strength for printing with FDM and was easily ground, heated and contoured by the orthotist. The weight of the 3D printed EBDB was only 50% of CAM based EBDB (Figure 1a-1c).

**Conclusion and Significance:** A sound FDM procedure using a standard structural factor of safety with FEA and ABS properties was implemented. The brace can be fitted by applying the traditional approach. The further research will improve bonding of ABS material that is prone to having horizontal cracks adjacent to the opening area.

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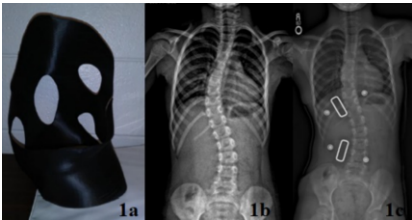


Figure 1a. EBDB with ABS material (Left); 1b and 1c: the major Cobb angle in AP out of brace was 41° (middle) vs. 28° in brace (right).

Effect of hole patterns on the biomechanical behavior of a brace

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**Introduction:** Cut-out-hole patterns are being implemented more frequently in brace designs to lighten the weight of the brace as well as to promote breathing of the skin. Typical shapes include triangles, diamond and circular geometry. Because these hole patterns remove material from the brace, the structural soundness of the brace is impacted. An optimal cut-out-hole pattern geometry is not obvious as there are several design parameters including stress, deformation and volume of material removed by the pattern.

**Objectives:** The purpose of this study was to quantify the effect of the various hole patterns on the structural efficiency of the brace and to determine the optimal pattern geometry.

**Methods:** A finite element model (FEM) of a patient’s brace was created using CAD modeling and geometry of the patient’s torso. A solid brace and multiple hole patterns (circular, diamond, triangle, hexagon and staggered hexagon) were modeled. The spacing between the holes, location of the pattern and the thickness of the brace was kept constant (2mm). Simulations were used to find the peak stress, peak deformation and volume of material removed by the holes.

**Results and Discussion:** The results of the simulation are given in Table 1. Note that from a previous study, in order to maintain corrective forces, the deformation cannot be more than 4.5 mm.[1] The pattern which meets the factor of safety requirement and gives the least amount of peak stress and deformation is the triangle pattern. However, this pattern removes the least amount of material. The hexagon pattern removes the most amount of material and has a peak deformation less than 4.5 mm.

**Conclusion and Significance:** The pattern which gives the least amount of peak stress and deformation is not necessarily the one which gives the lightest brace design. If the desire is to remove the most amount of material, then the hexagon pattern is preferable over the triangle pattern.

Table 1: Results of the simulations for various cut-out pattern

Pattern	Peak Deformation (mm)	Peak Stress (MPa)	Volume Removed (cm <sup>3</sup> )
None	4.50	2.86	0.00
Circle	5.50	4.90	30.28
Diamond	2.70	4.50	12.34
Hexagon	2.82	5.86	24.80
Hexagon (Staggered)	8.99	5.27	25.09
Triangle	2.53	3.52	12.34

**Reference:** 1. Rizza R, Liu XC, Thometz J, et al. Comparison of Biomechanical Behavior between a Cast Material and a Polyethylene Based Jacket. *Scoliosis*. 2015; 10(suppl. 2): S15:1-5.

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## Displacement and strain of the spine in the context of asymmetric pelvic bones

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**Introduction:** Asymmetry within the pelvic structure can lead to a cascade of postural compensations throughout the spine, predisposing people to recurrent somatic dysfunction and decreased functionality. As a basic structural element, the pelvis should be fully symmetric with respect to the sagittal plane. However, many studies conducted by different researchers showed, that an imbalance of the pelvis is very common. This conclusion was recorded based on various measurement types conducted by means of X-rays, CT as well as sectional preparations.

**Objective:** The aim of this research was to discover how the spinal column relates to the sagittal & frontal plane when there is a unilateral tilt of the pelvis in place.

The size of strain and displacement were not as significant as the change of shape itself during such altered conditions. The expected results were not found to be particularly complex, thus allowing an extremely simplified model of the human spine to be created. The developed models supporting structure and its sustaining stability attributes were assumed to be most important when situated in a vertical position.

**Methods:** In order to provide an analysis of the finite element method, a prototype model was developed replicating the concept of the vertebral body alternate with intervertebral discs shaped in the form of 'pole like' tubular sections (Figure 1). The model of the spine, having a physiological curvature, is fixed to the base which, in turn is placed in a mechanism replicating a tilt, relevant to an asymmetric position of the sacrum.

**Results and Discussion:** Simulations conducted in three various tilt positions resulted in the conclusion that strain on the scoliotic-ally deformed vertebral column occurs primarily in the intervertebral discs, whose elastic modulus is considerably lower than of vertebral bodies. It is worth mentioning that the largest accumulation of strain can be observed within the intervertebral discs T6-T7 and L2-L3. One can draw a conclusion that apical curves occur in the most curved regions of the spine, which results in multiplication of strain accumulation throughout these areas.

**Conclusion and Significance:** The greater the tilt of pelvic alignment, the higher the strain rates throughout the intervertebral discs and a larger scale of displacement of the vertebral column resulting in a higher degree of lateral curvature.

An asymmetric correlation of the pelvic bones may cause displacement and strain of the vertebral column, thus resulting in pathological changes such as scoliosis.

**References:** [1] Boulay C, Tardieu C, Benaim. Three-dimensional study of pelvic asymmetry on anatomical specimens and its clinical perspectives. *Journal Compilation of Anatomical Society of Great Britain and Ireland*. 200; 208: 21-33. [2] Debska B, Dluski M. Attempt of assessment of relation between asymmetry of pelvis and shape of scoliosis. *Journal of Orthopaedics Trauma Surgery and Related Research*. 2013; 32(2): 27-37. [3] Dluski M., Attempt of analysis of child ilium asymmetry in anteroposterior projection based on x-ray pictures. *Przegląd Lekarski*. 2007; 64: 28-31.

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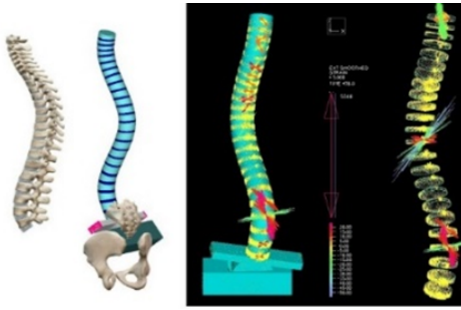


Figure 1. Model concept and strain distribution in the spine model with an inclined base.

## In vitro evaluation of sacroiliac joints motion during lower extremity maneuver

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**Introduction:** Sacroiliac joint (SIJ) as a source of pain is a common problem for athletes, especially in sports that involve repetitive loading or asymmetric loading of the pelvis with lower extremities in flexed position. One study on elite rowers found SIJ dysfunction occurred in 54% of team members.[1] Previous biomechanical studies largely focused on SIJ responses associated with loading via the spinal column or torso,[2] while little is known when loaded during maneuver of the lower extremity.

**Objective:** The objective was to investigate the 3D motion pattern at SIJs during unilateral internal rotation of the leg positioned at 90-degree flexion.

**Methods:** The hips from four freshly frozen human cadaveric lower torsos with thighs were tested (mean age 37yrs) on a custom-designed loading jig with the pelvis in an upright position. Each femoral epicondyle was exposed and potted onto a Plexiglas plate, which was used to manually impose internal rotation of the femur (up to 50 degrees) with the leg was positioned in 90° flexion and 0° adduction on a height-adjustable stance. A 6-dof load cell was bolted to the plate to measure the moments and forces generated during the maneuver. Three sets of marker triads from a motion tracking system were used to track motion at SIJs.

**Results and Discussion:** As the leg was internally rotated, SIJ motions increased with the applied torque in a close to linear fashion. The total SIJ rotation generated at 20 Nm of peak torque was higher in the contralateral SIJ ( $0.45 \pm 0.53$  degree), than the ipsilateral SIJ ( $0.26 \pm 0.22$  degree). The primary rotation of both SIJs was in the transverse plane in the direction of opening the ipsilateral joint posteriorly and contralateral joint anteriorly. Beside differences in rotation magnitude, the timing of the responding sacroiliac motion showed different patterns between the ipsilateral and contralateral sides. At the onset of the hip internal rotation, ipsilateral joint demonstrated a rapid increase in transverse rotation, while the contralateral joint increased at slower rate.

**Conclusion and Significance:** Findings from this study show that internal rotation of the femur imposes appreciable and asymmetric motion at SIJs and is proportional to the applied torsional load. This indicates that lower extremity maneuvers like those experienced in sports activities directly affect stability at these joints.

**References:** [1] Timm KE. Sacroiliac joint dysfunction in elite rowers *J Orthop Sports Phys Ther.* 1999; 29: 288-93. [2] Wang M, Dumas GA. Mechanical behavior of the female sacroiliac joint and the influence of the anterior and posterior sacroiliac ligaments under sagittal loads. *Clin Biomech.* 1998; 13: 293-9.

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## Effect of window cut-outs on the biomechanical performance of a torso jacket

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**Introduction:** There are numerous designs for a Thoraco-Lumbo-Sacral Orthosis (TLSO), often used in the treatment of scoliosis. Window cut-outs are used. A cut-out in the abdominal area is used to promote breathing. A window on the concave side of the spinal curve allows for spinal derotation. The minimum size and shape of each window is mandated by the anatomy of the patient. Improper sizing and placement of the window may lead to structural failure and/or impact the functionality of the brace.

**Objectives:** This study was to identify the biomechanical factors which justify the location, size and geometry of the window.

**Methods:** A finite element model (FEM) of a patient's brace was created using an optical scan of the brace. Multiple simulations were carried out to determine the optimal size and shape of the window (Figure 1) and the impact on the stress and deformation of the brace. In each iteration, the window size was increased, and the maximum stress and deformation of the brace were recorded.

**Results and Discussion:** Increasing the size of the windows by 8.4% lead to an increase in the maximum stress from 7.93 MPa to 7.97 MPa. Thus, we found that changing the size of the window had little effect on the maximum stress. However, increasing the size of the window affects the maximum deformation. For example, increasing the window size by 8.4% increased the deformation from 4.16 mm to 5.24 mm. From a previous study, in order to provide clinical function, the deformation cannot be more than 4.5 mm.[1] Thus, if the window size is increased by 8.4% the brace thickness should be increased from 4.00 mm to 4.34 mm.

**Conclusion and Significance:** Unlike the deformation, the stress in the brace is not significantly affected by the window size. Thus, deformation justifies the size of the window.

**Reference:** [1] Rizza R, Liu XC, Thometz J, et al. Comparison of Biomechanical Behavior between a Cast Material and a Polyethylene Based Jacket. *Scoliosis*. 2015; 10(suppl. 2): S15:1-5.

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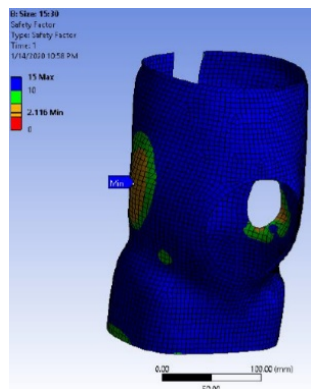


Figure 1. FEA provided with the maximal stress following change in size of brace abdominal window.

## On the efficient printing of a torso brace using multiple pieces

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**Introduction:** Additive Manufacturing or 3D printing (AM) is becoming popular in the manufacturing of braces. Compared to traditional methods the use of AM allows for the very accurate, fast manufacturing of a brace (in as little as 24 hours). Thus, there is minimal technician contact time reducing labor costs significantly. However, as the printing costs are directly related to the volume of material printed, and braces large, printing costs can be very high. One solution is to separate the brace into multiple pieces, print each piece separately and then assemble the pieces to form the complete brace.

**Objectives:** This purpose of this study was to determine the number of separate printed pieces and the orientations of these pieces which give the lowest printing time and cost for a brace.

**Methods:** Cost analysis based on brace volume was conducted using GrabCAD® (Stratsys, Eden Prairie, MN) on an existing patient's brace. Simulations were carried out with the brace cut horizontally so that the pieces retained their circular shape and vertically, so that the pieces were long and non-circular in shape (Figure 1). Several printers were considered (Fortus 380mc, Fortus 450mc, Fortus 900mc).

**Results and Discussion:** Vertical cut pieces required the most amount of print time (range: 15.62 hrs. to 21.03 hrs.), depending on the printer used and the number of pieces printed. The horizontal cut pieces required the least (9.57 hrs. to 9.92 hrs). The printing costs were higher for vertical pieces (range: \$187.61 to \$241.40) compared to horizontal pieces (range: \$109.67 to \$111.16). With respect to the printers, the number of pieces printed, the Fortus 900mc required the least amount of print time (9.57 hrs.) and the lowest printing cost (\$109.67) if 2 pieces are used.

**Conclusion and Significance:** There is an optimal number of separate pieces and orientation that will lead to the lowest printing time and cost. For the brace design under consideration, 2 pieces printed on a Fortus 900mc will give the lowest printing time and cost.

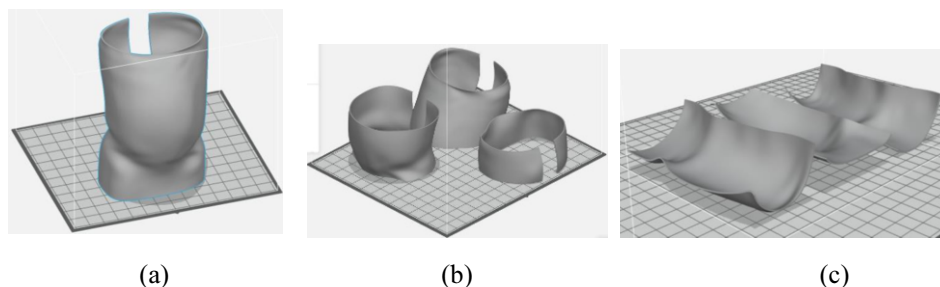


Figure 1: a) Complete brace, b) brace separated and printed into horizontal pieces and c) into vertical pieces.

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## Coordination pattern and variability in a flexion movement control test used in clinical assessment

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**Introduction:** Movement control (MC) tests are used in clinical practice to subgroup patients with non-specific chronic low back pain to adapt the treatment strategy based on whether they have a flexion or extension pattern. The underlying hypothesis is that impaired movement control and a lack of awareness of mal-adaptive movement pattern perpetuates LBP. It has already been shown that patients with LBP have impaired movement control.[1] Although these patterns can be assessed by some clinical tests, the validity of those tests has never been described by means of kinematics. Hence the purpose of this study was to examine the validity of these tests and to elucidate differences in spinal kinematics across participants. This will help explore if we can possibly use flexion MC tests from the Luomajoki test-battery to identify a Flexion Movement Pattern (FMP) in a wider population.

**Objectives:** The objective of this study was to compare spinal and pelvic kinematics between healthy participants with and without a FMP when completing a “waiters bow” assessment.

**Methods:** After necessary ethical approval, a sample of 29 adults (n=29, 14♀, 15♂, age 23.34 ± 2.32 year) were recruited to participate in this study. Based on a test-battery of 6 movement control tests designed by Luomajoki [1] they were divided into two groups: FMP group (n=16, 6♀, 10♂); No FMP group (n=13, 8♀, 5♂). Spinal kinematics whilst the participants performing a waiters bow (WB) were collected using a previously published protocol.[2]

**Results and Discussion:** There are differences in MC when the FMP and no-FMP group were compared (Figure 1). The lower thoracic region is more flexed in the FMP group during WB. Nevertheless, the results contradict the hypothesis that an earlier and more distinct flexion would show up in the lumbar region WB. In addition, there are clear variances in coordination pattern. Findings of the lumbar region contradict the hypothesis of a more flexed spine in the FMP since the FMP has more extension than the no-FMP.

**Conclusion and Significance:** Differences in spinal kinematics between participants of the FMP group and the non-FMP group exist, which demonstrate that the flexion MC tests from the Luomajoki test-battery could be used to identify a FMP in a wider group of patients. In addition, the individual variances could be used to design effective clinical management and assess the clinical outcome in a quantitative fashion.

**References:** [1] Luomajoki H, et al., Movement control tests of the low back; evaluation of the difference between patients with low back pain and healthy controls. BMC Musculoskelet Disord. 2008;9:170. [2] Needham R, et al. Multi-segment kinematic model to assess three-dimensional movement of the spine and back during gait. Prosthetics and Orthotics International DOI: 10.1177/0309364615579319, 2015

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\* Corresponding author.

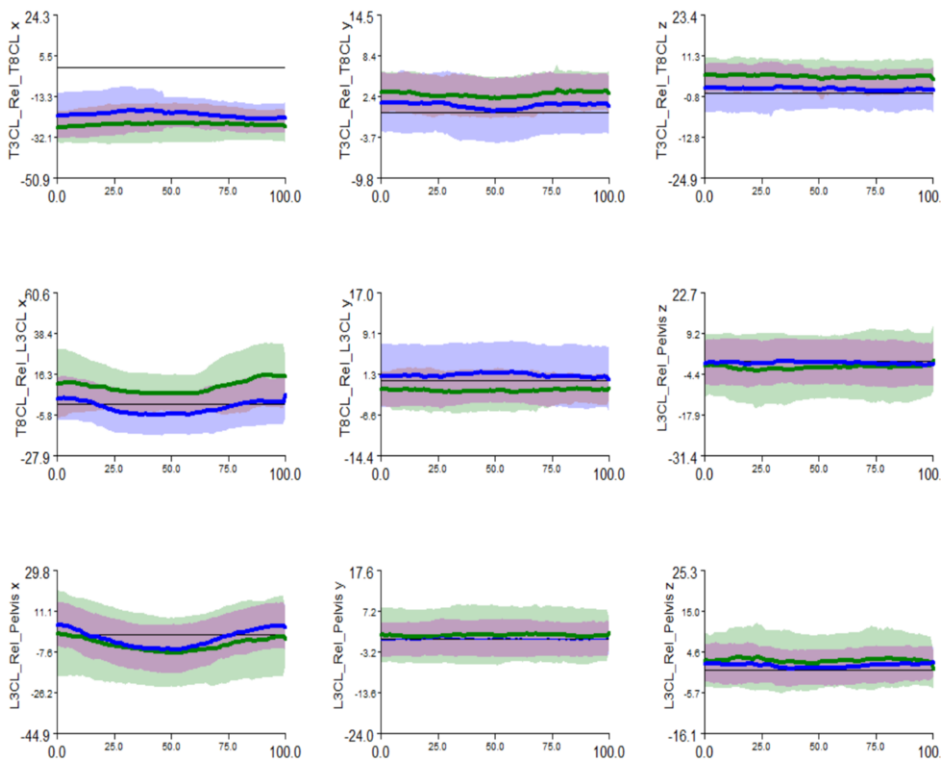


Figure 1: Spinal kinematics of the FMP group (blue) and the no-FMP group (green) during waiters bow in the sagittal, frontal and transverse plane. Three regions of the spine are presented: UTR(T3 vs. T8), LTR(T8 vs L3) and LR(L3 vs pelvis). Legend: flex/ext=flexion(-angle)/extension(+angle); lat.flex=left(-angle)/right(+angle) lateral bending; rotation=right(-angle) and left (+angle) rotation.

## Assessment of three-dimensional movement of the spine and pelvis during routine clinical assessment

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**Introduction:** Individuals with movement coordination impairment (MCI) experience poor control of spine and pelvis and often develop a compensatory movement strategy. Currently there is a paucity of information on differences in segmental kinematics to help understand the adopted movement strategy and its link to commonly used clinical assessment.

**Objective:** The current pilot study is aimed at investigating the usability of a cluster spine model to assess the clinically relevant assessment, such as one-leg standing.

**Methods:** After necessary ethical approval, nine healthy subjects, (6 men, 3 female, 22±2.0 years, 177±7.4 cm, 69±8.7 kg) were recruited to participate in the study. The marker configuration was in accordance with Needham et al.[1]. Subjects were instructed to complete 2 variants of a one-leg standing task. In both tasks they stood relaxed on both feet and were either instructed to flex the knee (90°) without hip extension (backward lifting) or to flex both hip and knee to 90° (forward lifting), starting with the right leg and followed by the left leg. Data were collected with an 8 camera opto-electronic system (Oqus, Qualisys, Göteborg, Sweden) at 100 HZ and processed in Visual3D (C-Motion Inc., Germantown, MD, USA). Motion from the upper (T3) versus lower thoracic spine (T8), from lower thoracic versus lumbar spine (L3) and between the lumbar spine and the pelvis was analyzed for 3 valid trials per subject.

**Results and Discussion:** In the sagittal plane the main differences are seen (Figure 1) in the lumbar spine versus the pelvis, while at the higher regions, the spine is quite stable only showing minor differences. In the frontal plane the upper thoracic region shows (Figure 1) little movement, where the lower thoracic and the lumbar regions bend to the opposite side of the lifted leg. This is more pronounced during forward lifting. Rotational movements are seen in all three regions. The direction of rotation for forward leg lifting is opposed to the one during backward lifting. This is the first study to document the spine kinematics of different regions during tasks suggested for clinical assessment, e.g. two variants of one-leg standing. Future research should aim at testing more subjects, other clinically relevant movements and comparing healthy subjects with patient populations.

**Conclusions and Significance:** Whilst the 3D cluster spine model seems to be a useful tool to document the spine kinematics, the results highlight quantitative differences which needs be considered to develop effective clinical management.

**References:** [1] Needham R, Naemi R, Healy A, et al. Multi-segment kinematic model to assess three-dimensional movement of the spine during gait. *Prosthetics and Orthotics International*. 2015; 40(5): 624-635.

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\* Corresponding author.



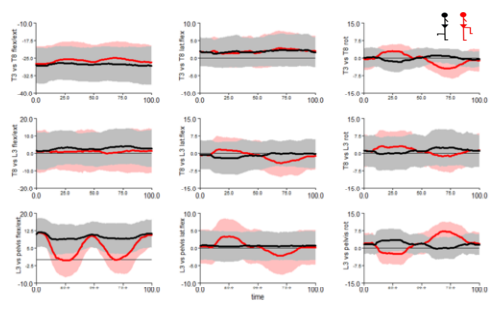


Figure 1: Mean spine kinematics during leg lifting (red = forward lifting , black = backward lifting)

## Quantifying three-dimensional lumbar kinematics during gait using optoelectronic motion capture: a comparison of two kinematic models

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**Introduction:** Adolescent Idiopathic Scoliosis (AIS) can result in visible deformity, pain, psychological morbidity, and can have a significantly impact on walking gait. Optoelectronic marker-based systems are the gold standard for gait analysis. However, conventional gait models are often used in scoliotic gait research that do not consider movement in the lumbar spine. Furthermore, placing markers on the spinous processes of lumbar vertebrae limits analysis in the sagittal and frontal plane. More recently, it has been proposed that a skin mounted 3D cluster attached over a spinous process can reduce relative error during the tracking of movement since the markers are in a fixed position<sup>1,2</sup>.

**Objective:** This preliminary study compared two kinematic modelling approaches that quantify three-dimensional movement (3D) in the lumbar region during gait, that could inform on clinical management strategies for people with AIS.

**Methods:** After necessary ethical approval, ten male participants with no history of musculoskeletal impairments took part in this study. Marker coordinate data was recorded at 100 Hz using an eight-camera motion capture system (VICON, Oxford, UK). For model one<sup>3</sup> individual markers were attached over the spinous processes of L1 and L5, in addition to two markers attached on to the back-surface either side of L1. For model two<sup>2</sup> a 3D cluster was used, which consists of three markers positioned in a nonlinear configuration that are attached to a semirigid base and was attached over the spinous process of L3. Both kinematic models were constructed in Visual3D (C-Motion, Inc., Germantown, MD, USA) and segment angle data was processed using a low-pass Butterworth filter with a cut-off frequency of 6 Hz. Statistical parametric mapping analyses were applied to kinematic waveform data to compare angles in a time-domain<sup>4</sup>.

**Results and Discussion:** While the kinematic waveform profiles of the two models were similar in all three planes of motion, a significant difference was noted in the transverse plane, with model two resulting in a greater range of motion compared to the model one. This is contrary to the notion of relative error, thus, greater range of motion reported for model two may relate to the structural design of the 3D cluster. The semi-rigid base plate was of an appropriate size to ensure the 3D cluster was less susceptible to excessive perturbation to discard the possibility of ‘wobble’<sup>2,5</sup>. Nevertheless, while the semi-rigid base plate conformed to the back surface, movement of the lateral sides of the base plate due the predisposed influence of para-spinal musculature, could have affected the estimation of axial rotation. While 3D clusters are a reliable technique when implemented in the same laboratory<sup>5</sup>, the 3D cluster used in the current study was handmade, which poses a challenge to accurately replicate in another gait laboratory. Therefore, to allow replication and for validation purposes, it is proposed that future comparative studies use a 3D printed cluster to remove the limitations of hand-built clusters and to provide a standardised structure<sup>6</sup>.

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**Conclusion and Significance:** The results of this study emphasise the usefulness of a 3D cluster approach to assess regional and localised range of motion. To facilitate this, it is recommended that future studies use a 3D printed cluster to provide a standardised structure to allow study replication and validation across gait laboratories. This will help in quantifying outcomes that will facilitate effective clinical management.

**References:** [1] Needham et al. *Stud Health Technol Inform*, 176, 151-4, 2012. [2] Needham et al. *Prosthet Orthot Int*, 40, 624-635, 2016. [3] Crosbie et al. *Gait Posture*, 5, 6-12, 1997. [4] Pataky. *Comput Methods Biomech Biomed Engin*, 15, 295-301, 2012. [5] Needham et al. *J Med Eng Technol*, 40, 172-85, 2016. [6] Needham et al. *Scol Spine Deform*, 12, 1, 2016.

## Cervical kyphosis in patients with thoracic idiopathic scoliosis

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**Introduction:** Cervical kyphosis is common finding in patients with idiopathic scoliosis (IS). Due to three-dimensional nature of IS deformation the sagittal alignment of the spine is impaired. It affects adjacent segments of the spine and provokes compensation mechanisms. However, not all patients with IS reveal sagittal alignment changes in the cervical spine.

**Objective:** To determine association of cervical kyphosis with sagittal alignment of adjacent segments of the spine.

**Methods:** Fifty-eight patients with the thoracic major curvature 71.2°, range 48°-106°, Lenke classification type 1 or 3, 17 males and 41 females, mean age 14.6 ± 1.9 were included. Standing AP and lateral with maintained horizontal gaze (chin-brow vertical angle CBVA ≤ 15°) X-rays were analyzed. Cervical sagittal profile (CSP), based on cervical centroid position was classified as lordotic, straight, sigmoid or kyphotic according to Ohara et al. [1]. Patients were divided into two groups: kyphotic (kyphotic or sigmoid CSP) or non-kyphotic (lordotic or straight CSP). The groups were matched for age, gender and curves magnitude, Table 1. The following measurements were performed: Cobb angle, pelvic incidence, sacral slope, pelvic tilt, sagittal vertical axis (SVA), L1-S1 lordosis, T11-L1 lordosis, T1-T12 kyphosis, T4-T12 kyphosis, T1-T4 kyphosis, T1 slope, thoracic inlet angle (TIA), neck tilt (NT), cranial tilt, cervical sagittal vertical axis (cSVA), C2-C7 lordosis, C0-C2 lordosis, CBVA. The spine alignment was compared between groups with 0.05 as a statistically significant threshold.

**Results and Discussion:** The cervical kyphotic CPS was found in 48.3% (N=26), sigmoid 5.1% (N=3), straight 37.9% (N=22) and lordotic 12.1% (N=7).

Although, C2-C7 lordosis differed significantly, there was no difference in C0-C2 lordosis between groups  $p=0.0001$  and  $p=0.2488$ , respectively. There was no difference for cSVA and cranial tilt between the groups. The most important difference was found in T1 slope, however others thoracic inlet parameters (NT and TIA) did not differ significantly. Global thoracic kyphosis as well as proximal and distal thoracic kyphosis were significantly lower in patients with cervical kyphosis,  $p=0.0024$ ,  $p=0.0234$  and  $p=0.0417$ , respectively. The measure of global compensation expressed with the SVA was negative in kyphotic patients and positive in non-kyphotic patients  $p=0.0009$ . Patients with cervical kyphosis revealed significantly lower pelvic incidence  $p=0.0047$ , Table 1.

**Conclusions:** T1 slope revealed the parameter the most significantly associated with presence of cervical kyphosis. The sub-occipital cervical spine seems to be not affected by cervical kyphosis. Cervical kyphosis may be associated with congenital predisposition as observed by pelvic incidence difference.

Table 1. Sagittal spine alignment for thoracic idiopathic scoliosis patients with cervical kyphosis

	Kyphotic N=29		Non-kyphotic N=29		P
	Mean±SD	Min - max	Mean±SD	Min - max	
Age (y.o.)	14.4±1.9	(11-19)	14.9±1.9	(12-18)	0.3175 <sup>1</sup>
Gender (F:M)	23:6		18:11		0.2486 <sup>2</sup>
Lenke 1:Lenke 3	17:12		15:14		0.7918 <sup>2</sup>
Proximal thoracic Cobb angle (°)	30.8±8.5	(16-44)	31.8±8.0	(14-43)	0.6210 <sup>1</sup>
Main thoracic Cobb angle (°)	70.8±9.8	(53-97)	71.7±14.8	(48-106)	0.7846 <sup>1</sup>
Lumbar Cobb angle (°)	47.1±18.5	(21-97)	44.5±17.6	(38-105)	0.5850 <sup>1</sup>
Pelvic incidence (°)	43.7±9.2	(23-59)	51.9±11.7	(29-72)	<b>0.0047<sup>1</sup></b>
Sacral slope (°)	36.2±9.3	(9-58)	41.1±11.2	(20-55)	0.0746 <sup>1</sup>
Pelvic tilt (°)	7.7±5.1	(-1-20)	10.7±10.0	(6-45)	0.1657 <sup>1</sup>
SVA (mm)	-20.8±26.0	(-73-35)	4.1±27.7	(-36-55)	<b>0.0009<sup>1</sup></b>
L1-S1 lordosis (°)	52.3±10.8	(28-74)	56.7±11.9	(25-79)	0.1478 <sup>1</sup>
Th11-L1 lordosis (°)	-4.3±10.2	(-29-8)	-1.5±9.8	(-25-12)	0.1905 <sup>3</sup>
Th1-th12 kyphosis (°)	23.8±10.6	(2-41)	31.8±8.3	(10-48)	<b>0.0024<sup>1</sup></b>
Th4- th12 kyphosis (°)	16.4±8.6	(-5-31)	21.4±9.6	(1-40)	<b>0.0417<sup>1</sup></b>
Th1- th4 kyphosis (°)	7.4±4.7	(-1-18)	10.4±4.9	1-21	<b>0.0234<sup>1</sup></b>
T1 slope (°)	8.9±6.5	(-2-21)	16.5±5.8	(5-27)	<b>0.0001<sup>1</sup></b>
TIA (°)	52.0±8.3	(32-71)	56.6±9.7	(34-80)	0.0612 <sup>1</sup>
Neck tilt (°)	42.5±8.6	(29-57)	40.1±10.0	(24-57)	0.4330 <sup>1</sup>
Cranial tilt (°)	6.9±5.8	(-1-25)	5.7±5.2	(-2-15)	0.4524 <sup>1</sup>
cSVA (mm)	16.5±14.1	(-36-37)	16.9±11.8	(1-44)	0.8893 <sup>1</sup>
C2-C7 lordosis (°)	-9.5±10.8	(-32-3)	5.6±8.1	(-4-20)	<b>0.0001<sup>1</sup></b>
C0-C2 angle (°)	29.6±9.2	(12-50)	27.0±7.0	(11-41)	0.2488 <sup>1</sup>

<sup>1</sup>t – Student, <sup>2</sup>Chi<sup>2</sup>, <sup>3</sup>U – Mann – Whitney; p<0.05 **bolded**; thoracic inlet angle (TIA); sagittal vertical axis (SVA); cervical sagittal vertical axis (cSVA); chin-brow vertical angle (CBVA); non-kyphotic (lordotic and stright CSP); kyphotic (kyphotic and sigmoid CSP); CSP – cervical sagittal profile

## References

- [1] Ohara A, Miyamoto K, Naganawa T, Matsumoto K, Shimizu K. Reliabilities of and correlations among five standard methods of assessing the sagittal alignment of the cervical spine. *Spine (Phila Pa 1976)*. 2006; 31(22): 2585-91; discussion 2592.

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# Chapter 14

## Abstracts for 3D Imaging Measurements

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Cervical spine sagittal alignment in patients with idiopathic scoliosis  
Lenke type 1 versus type 3

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**Introduction:** Cervical spine alignment in idiopathic scoliosis (IS) has been extensively studied for the most common Lenke type 1 curvature. However, the major thoracic curvature is present in both Lenke 1 (main thoracic) and Lenke 3 (double major) scoliosis. The latter was much less studied so the impact of structural lumbar curvature on the cervical spine alignment needs more extensive evaluation.

**Objective:** To determine differences in cervical spine sagittal alignment in Lenke 1 versus Lenke 3 IS.

**Methods:** Fifty-eight patients, 17 males and 41 females, mean age 14.6 ±1.9 were attributed to either Lenke type 1 curve (N=31) or Lenke type 3 (N=27). Standing AP and lateral with maintained horizontal gaze (chin-brow vertical angle CBVA ≤15°) X-rays were analyzed. The following measurements were performed prior to and one week after thoracic curve surgery: CBVA, C0-C2 lordosis, C2-C7 lordosis, cervical sagittal vertical axis (cSVA), cranial tilt, neck tilt (NT), thoracic inlet angle (TIA), T1 slope and Cobb angle. The parameters were compared between groups with 0.05 as a statistically significant threshold.

**Results and Discussion:** The groups were matched for age, gender and thoracic curve magnitude. The difference was in lumbar curvature, Table1.

Neither the sub-occipital cervical lordosis (C0-C2 lordosis) nor the distal cervical lordosis (C2-C7 lordosis) differed between the groups. However, the Lenke 3 group revealed lower cranial tilt (4°) and cSVA (10mm), p=0.0026 and p=0.0042, respectively, what can be interpreted as a measure of the head protraction. The thoracic inlet parameters (TIA, NT, S1 slope) were comparable in both groups, Table

**Conclusions and Significance:** The proximal and distal cervical lordosis, as well as thoracic inlet parameters are comparable between Lenke 1 and Lenke 3 patients. However, cervical compensation parameters such as cSVA and cranial tilt may differ between patients with Lenke 1 and Lenke 3 idiopathic scoliosis.

Table 1. Cervical spine sagittal alignment for idiopathic scoliosis Lenke type 1 vs. type 3

	Lenke 1 N=31		Lenke 3 N=27		
	Mean±SD	Min - max	Mean±SD	Min - max	P
Age (y.o.)	14.6±1.8	(12-18)	14.7±2.0	(11-18)	0.9154 <sup>1</sup>
Gender (F:M)	21:10		20:7		0.8109 <sup>2</sup>
Main thoracic Cobb angle (°)	69.9±9.8	(52-95)	73.±15.1	(48-106)	0.2731 <sup>1</sup>
Lumbar Cobb angle (°)	32.9±7.4	(18-46)	59.2±16.6	(36-105)	<b>0.0001</b> <sup>3</sup>
CBVA (°)	6.4±5.7	(-11-15)	5.2±7.6	(-14-15)	0.4960 <sup>1</sup>
C0-C2 angle (°)	28.1±7.8	(11-43)	28.4±7.0	(12-50)	0.9462 <sup>3</sup>
C2-C7 lordosis (°)	-1.9±12.1	(-29-18)	-2.3±12.3	(-32-20)	0.9132 <sup>1</sup>
cSVA (mm)	21.1±10.9	(-9-44)	11.5±13.3	(-36-37)	<b>0.0042</b> <sup>1</sup>
Cranial tilt (°)	8.2±5.1	(-1-25)	4.1±5.2	(-2-17)	<b>0.0026</b> <sup>3</sup>
TIA (°)	54.5±9.9	(34-80)	54.0±8.5	(32-71)	0.8358 <sup>1</sup>
Neck tilt (°)	41.1±10.2	(26-64)	42.1±8.4	(24-57)	0.6808 <sup>1</sup>
T1 slope (°)	13.5±7.7	(-2-26)	11.7±6.5	(1.1-24.0)	0.3676 <sup>1</sup>

<sup>1</sup> t – Student, <sup>2</sup> Chi<sup>2</sup>, <sup>3</sup> U – Mann – Whitney; p<0.05 **bolded**; thoracic inlet angle (TIA); cervical sagittal vertical axis (cSVA).

## Reliability of ultrasound reflection coefficient measured on ultrasound images for children with Adolescent Idiopathic Scoliosis

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**Introduction:** Children with AIS and low bone quality may have higher risk of curve progression. Current bone quality assessment method does not evaluate directly from the spine region. We developed a new approach to capture the ultrasound (US) reflection coefficient (RC) signals which may relate to bone quality from the spine. We have demonstrated that the RC value had a moderate correlation with curve severity ( $r^2 = 0.42$ ) in a previous study.

**Objective:** To investigate the reliability of US reflection coefficient (RC) measured on US spine images in children with AIS.

**Methods:** Thirty children with AIS (24 F; 6 M) aged  $14.0 \pm 1.7$  years old were consented and recruited. All participants were scanned by an US imager twice in standing positions. The raw US data were acquired and used to calculate the RC value. A custom software was developed to export the RC value automatically after the region of interest (ROI) was selected. Since the L5 is the least rotated vertebra and the lamina region reflected the strongest ultrasound signals, a rater selected the ROI around the lamina based on the US image. At each scan, approximately 25 frames of US images covered the lamina region of a single vertebra. A rater selected 5 frames within the 25 frames and identified the strongest RC values on both left and right laminae from each scan. RC values extracted from the first and second scans were extracted in a week apart to eliminate memory bias. The maximum RC value from the first and second scans were compared. The Pearson correlation coefficient ( $r$ ), intra-class correlation coefficient (ICC [2,1]) and standard error of measurement (SEM) were reported.

**Results and Discussion:** Among 30 images, 6 images were eliminated because of the unclear images on the L5 region. The mean  $\pm$ SD of the maximum RC value for the first versus second scan were  $0.20 \pm 0.09$  vs  $0.20 \pm 0.11$ . The mean  $\pm$ SD of the maximum RC values of the first versus second scan from the 1<sup>st</sup> week and the 2<sup>nd</sup> week were ( $0.20 \pm 0.09$  vs  $0.20 \pm 0.11$ ) and ( $0.21 \pm 0.11$  vs  $0.20 \pm 0.09$ ), respectively. Overall, a moderate to good correlation and intra-rater reliability on RC index between scan 1 and 2 were found with  $r^2 \geq 0.51$  and ICC [2,1]  $\geq 0.72$ . The overall SEM values between all measurements was  $\leq 0.03$ . Clinical application on using RC index to predict progression of scoliosis will be explored.

**Conclusion and Significance:** There was a moderate to good correlation ( $r^2 \geq 0.51$ ) and reliability (ICC [2,1]  $\geq 0.72$ ) of RC index between the two repeated scans. The axial vertebral rotation may affect the RC measurements. The application of the RC value to predict progression of scoliosis will be performed in the near future.

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\* Corresponding author.

## Implication of head position on global sagittal alignment of Adolescent Idiopathic Scoliosis with and without thoracic hypokyphosis after posterior spinal fusion

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**Introduction:** The purposes of this study was to identify global sagittal alignment (GSA) in adolescent idiopathic scoliosis (AIS) with and without thoracic hypokyphosis (THK) after posterior spinal fusion and further follow-up, in comparison with asymptomatic controls (NC).

**Methods:** 27 operative AIS girls with a major right thoracic curvature and 36 female asymptomatic controls (NC) were recruited. AIS were subdivided into THK and normal thoracic kyphosis (NTK). Biplanar stereoradiographies were acquired at baseline, immediate post-operatively, 1-year and 2-year follow-up. Measurement on multiple GSA parameters and head positions, including ratio of sagittal vertical axis to sacro-femoral distance (SVA/SFD) and angle of odontoid-hip axis (OD-HA) line, were done.

**Results and Discussion:** Significant differences on multiple GSA parameters between AIS, with and without THK, and NC were found. Compared with NC, AIS with THK at baseline had higher SVA/SFD ( $p < 0.05$ ) and OD-HA ( $p < 0.05$ ), indicating that THK had compensated balance with unusual forward leaning posture. After immediate post-operative, SVA/SFD still remained high while OD-HA reversed, suggesting balance remained partially compensated. Both parameters were normalized after 2-year follow-up, indicating sagittal balance finally achieved. In contrast, there was no significant difference between NTK and NC.

**Conclusion and Significance:** The surgical treatment significantly restored the thoracic kyphosis. Changes in GSA and mechanism of balance are totally different in AIS with or without THK. As the head plays as a critical role on balance during immediate and delayed post-operation, OD-HA can be a complementary parameter for assessing the global balance during post-operative follow-up of AIS patients with THK.

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## The method for measurement of three-dimensional angle of scoliosis from standard radiographs

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**Introduction:** Three-dimensional angle of idiopathic scoliosis cannot be accurately assessed with a one plane parameter – Cobb angle.

**Objective:** To propose a novel method for evaluation of the three-dimensional angle of scoliosis based on two standard x-rays (standing PA and lateral) which consists of the measurement of the angle between the upper endplate of the upper-end vertebra and the lower endplate of the lower-end vertebra (3D scoliosis angle).

**Methods:** The 3D-angle of 30 curves was measured with either Computer Tomography (CT) or Digital Reconstructed Radiographs (DRRs): PA and lateral. CT was used as a reference. In the case of CT, the 3D-angle was calculated based on the coordinates of triple points situated on the upper endplate and the triple points situated on the lower endplate of the scoliosis curve. In the case of DRR, the 3D-angle was calculated using the four angles formed by the endplates of the curve with the horizontal plane. These angles were measured on the PA and lateral projection of the spine. The reliability and reproducibility for the 3D-scoliosis angle measurements were tested with the Intraclass Correlation Coefficient (ICC) with the use of PA and lateral x-rays of 31 patients which gave 62 curves in total.

**Results and Discussion:** There was no significant difference between the 3D-angle measurements obtained with DRR versus CT,  $p > 0.05$ . There was a significant difference between the 3D-scoliosis angle and the Cobb angle measurements performed based on the x-rays. The reproducibility and reliability for 3D-angle measurements were high.

**Conclusion and Significance:** Based on two standard radiographs, PA and lateral, it is possible to calculate the 3D-angle of scoliosis [Figure].

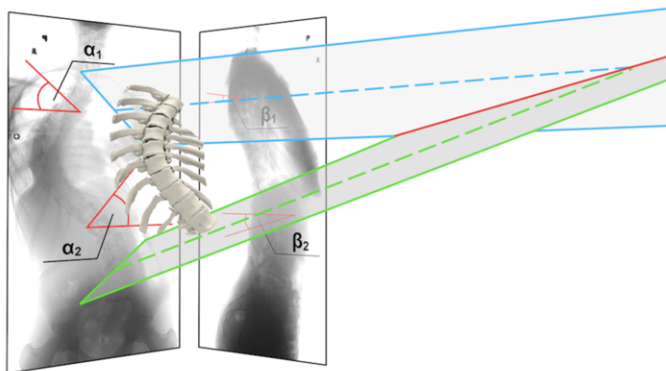


Figure. The angle between the intersecting (spotted) lines is a 3D-scoliosis angle;  $\alpha_1$ - the angle between the line parallel to the upper endplate of the upper-end vertebra and the ground line measured in the coronal plane;  $\alpha_2$ - the angle between the line parallel to the lower endplate of the lower-end vertebra and the ground line measured in the coronal plane;  $\beta_1$ - the angle between the line parallel to the upper endplate of the upper-end vertebra and the ground line measured in the sagittal plane;  $\beta_2$ - the angle between the line parallel to the lower endplate of the lower-end vertebra and the ground line in the sagittal plane.

### 3D classification of the right thoracic scoliotic spine by using only two view spinal radiographs: a validation study

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**Introduction:** the current classification of AIS is based on the frontal shape of the spine with one sagittal modifier. Such classification does not consider the variations in the 3D curvature of the spine. The current 3D classifications are complicated and required specific/ programs tools which does not fit in the daily clinical routine. A 3D AIS classification that can be used readily in clinics is of critical need.

**Objective:** Develop a 3D classification for right thoracic AIS that can be used in orthopedic clinics.

**Methods:** We used a previously mathematically developed 3D classification of the right thoracic scoliotic spine and determine the variations in the sagittal, frontal characteristics of the subtypes.[1,2] We then asked 5 observers to use these characteristics to classify a cohort of the 40 right thoracic patients according to this 3D classification using their frontal and sagittal radiographs. The percent belonging of each spine to one of the previously spinal subtypes were determined mathematically. The manual classification was compared to the numerical 3D classification of the same cases. The agreement between the five raters was evaluated.

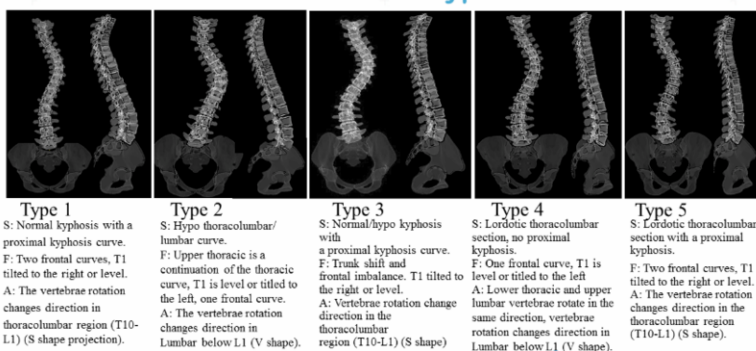
**Results:** A total of 8 patients belonged to one of the pre-existing clusters only at 33% or lower probability. Excluding these patients, the inter observer reliability was excellent, kappa=0.63, p=0.024 using the Fleiss' Kappa method. Our classification method showed promising result to implement 3D AIS classification without the need for image processing or analytic methods.

**Conclusion:** Excellent agreement was observed between the raters in 3D classification of the spine using the two-view X-rays. This classification method has the potential to be incorporated in orthopedic clinics to better appreciate the differences between the 3D curve types in AIS.

References:

1. Pasha S, Hassanzadeh P, Ecker M, Ho V. A hierarchical classification of adolescent idiopathic scoliosis: Identifying the distinguishing features in 3D spinal deformities. PLoS One. 2019; 14(3):e0213406. doi:10.1371/journal.pone.0213406.
2. Pasha S, Baldwin K. Surgical outcome differences between the 3D subtypes of right thoracic adolescent idiopathic scoliosis. Eur Spine J. 2019. doi:10.1007/s00586-019-06145-4

#### Characteristics of the five subtypes of thoracic curve



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# Chapter 15

## Abstracts for Non-Surgical Intervention

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## Effect of casting in the treatment of Early Onset Scoliosis

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**Introduction:** Early onset scoliosis (EOS) is a challenging diagnosis given its propensity to progress and have effects on other organ systems. Casting, including use of Risser body casts (RBC) and elongation derotation flexion (EDF) casts, is a common treatment to attempt to delay surgical treatment or cure EOS.

**Objective:** Determine the quantitative improvement in Cobb angle, rib-vertebral-angle difference (RVAD), vertebral rotation (VR) by Nash-Moe method, thoracic height (TH) and width (TW) seen after casting of EOS.

**Methods:** A total of 34 patients with EOS were recruited at the beginning of the study, and of 26 (11 females, mean age of 21.4 months) were followed through the course of their casting treatment (mean 17 months, 7 casts). Patients were excluded if they did not have a final out of cast X-ray. Ten patients had body casts while 16 had EDF casting. Cobb angle, RVAD, and VR were measured pre-casting, in the first cast, and out of cast after the final cast. Analysis of variance and local regression methods were used to determine statistical differences over time.

**Results and Discussion:** The first cast improved the major Cobb angle by a mean of 20.2° compared to the pre-casting value ( $p < 0.001$ ). Final out of cast Cobb angle improved on average 17.0° from pre-casting levels ( $p < 0.001$ ). Children with less severe involvement (i.e. lower initial Cobb angle) tended to have more relative improvement than those with more severe involvement (greater initial Cobb angle), as noted by the change in the local regression slope (Figure 1). This is consistent with other studies showing that smaller initial Cobb angle is predictive of improved outcome.[1] Additionally, the final cast significantly improved the RVAD (7.6°) and VR (0.5) compared to the pre-casting value ( $p < 0.05$ ) while continuously growing in TH (18.9 cm) and TW (7.9 cm) ( $p < 0.05$ ).

**Conclusion and Significance:** Casting is an effective method for improving the Cobb angle in most patients. Severely affected patients will likely still require surgical management, though casting will often delay the course. Future work should begin to explore factors that predict success to help prescribe a patient-specific approach to care of EOS.[2]

**References:** [1] Fedorak GT, D'Astous JL, Nielson AN, et al. Minimum 5-year Follow-Up of Mehta Casting to Treat idiopathic Early Onset Scoliosis. *JBJS*. 2019; 101(17):1530. [2] Grzywna A, McClung A, Sanders J, et al. Survey to describe variability in early onset scoliosis cast practices. *J Child Orthop*. 2018; 12(4): 406.

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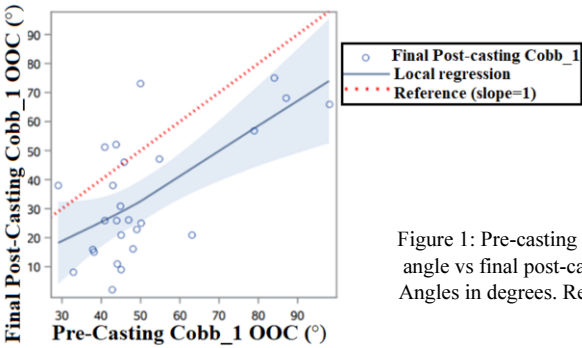


Figure 1: Pre-casting out-of-cast (OOC) major Cobb angle vs final post-casting major Cobb angle OOC. Angles in degrees. Reference line would indicate no change.

## Upper thoracic counter-tilt – a novel measure of in-brace correction in adolescent idiopathic scoliosis with proximal thoracic curves

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**Introduction:** The main goal of brace treatment is to stop the curves from progression or at least to the surgical range. The quality of a brace is commonly judged by the amount of an in-brace Cobb angle correction. In-brace correction equals to the difference of the Cobb angle out-brace and Cobb angle in-brace divided by the Cobb angle out-brace and is expressed in percentages. It is commonly believed that the in-brace correction of the major curve must reach at least 50% for a brace to be considered of a good quality. However, in case of proximal thoracic structural curves, more correction of the major thoracic curve usually leads to the proximal curve progression. These proximal thoracic curves are among the most difficult curves to treat, the prognosis is often poor, and there is a high risk of brace failure, especially with low brace quality and poor brace-wearing compliance. Recognizing this problem, some authors have suggested that striving for  $\geq 50\%$  in-brace correction may not be the optimal solution. However, there has been no consensus as to what constitutes an optimal in-brace correction.

**Objective:** To describe the upper thoracic counter-tilt (UTC) as a novel measure of assessing the brace quality with respect to the individual maximum correction in the presence of proximal thoracic curves.

**Methods:** Fifty patients with AIS having major thoracic and proximal thoracic curves were randomly selected from a database. Their out-of-brace and corresponding in-brace Cobb angles and UTC were measured. UTC was measured as the inclination of the upper end vertebrae of the proximal thoracic curve and the horizontal. We assessed the correlation between the Cobb and the UTC using the Pearson correlation coefficient.

**Results and Discussion:** The in-brace Cobb angle was negatively correlated with UTC, such that the smaller the in-brace Cobb angle the larger the UTC.

**Conclusion and Significance:** Fifty percent in-brace correction of the major curve is a main stay to judge the quality of a brace. However, it may be more prudent to seek the optimal correction for a given patient especially in the presence of proximal thoracic curves, rather than striving to reach an arbitrary number. We propose routine measurement of the upper thoracic counter tilt (UTC) both in out-of-brace and in-brace radiographs as an additional measure of a brace quality to better inform clinical decision making.

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## The experiences and effectiveness of the Spinecor brace on older adults with degenerative scoliosis: a mixed methods pilot study

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**Introduction:** This paper details the qualitative experiences together with the quantitative effects of a mixed methods study into the SpineCor brace on older adults with degenerative scoliosis.

**Objectives:** The primary objective of this mixed methods study was to explore the qualitative experiences of wearing a Soft SpineCor brace in Older Adults (over 50 years old) with Degenerative Scoliosis. The secondary objective was to conduct a pilot study evaluating the quantitative effectiveness of the brace using different pain and quality of life questionnaires.

**Methods:** Participants: For the participants to be eligible for this part of the overall study, they were required to have worn the brace for 6-months (Figure 1). This time point was selected as it was believed by clinicians that it would be where the most noticeable changes in the patients' health and pain scores would be observed. Furthermore, 6 months gave enough time for any initial teething problems with wearing the brace to be identified and resolved, as well as allowing the patients to reflect on their experiences of wearing the brace over a reasonable period of time. Due to significant problems with recruiting patients, only eight participants; 1 male and 7 female aged 55 and over participated in this study. Instrumentation: The spinecor brace used on the older adults was similar to the one used in young patients with adolescent idiopathic scoliosis reported in the literature. Procedure: All the participants were interviewed and completed the questionnaires. The data gathered from the interviews was then analysed using a top down approach with themes and subthemes being extracted.

**Results and Discussion:** The results showed that the main experiences of living with scoliosis in people over 50 was one of constant pain and limited activity levels. The interviews also identified the benefits patients experienced whilst wearing the brace along with the previously unknown functional problems associated with wearing the brace such as the comfort and practicalities of the brace design. As a result of the findings of this study, the SpineCor company changed the design of their brace to try to resolve the functional problems that the participants in this study experienced. The results from the quantitative questionnaires were compared with those from the control group who did not receive the SpineCor brace. Overall, we found that the patients who wore the brace, when interviewed, reported improvements in their pain and quality of life.

**Conclusions and significance:** The main experiences of living with scoliosis in people over 50 was one of constant pain and limited activity levels. The results suggest that the Spinecor brace is effective in reducing pain and improving the quality of life in older people with degenerative scoliosis. These preliminary results suggest that providing a soft brace to older people with degenerative scoliosis may help to decrease pain and improve quality of life.

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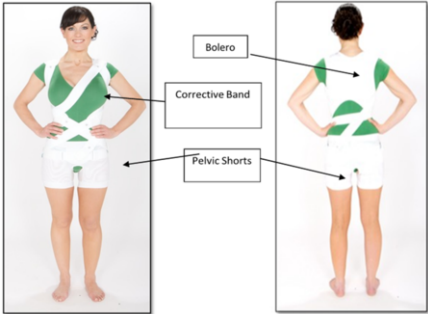


Figure 1. AP view of a Soft SpineCor brace.

## The use of Torso Measurement Frame to create an Elongation Bending Derotation Brace in juvenile scoliosis during standing

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**Introduction:** In our previous study, children with juvenile scoliosis who are willing to cooperate with trunk manipulation and able to stand firmly were surrounded and treated by at least two clinicians: holding bilateral arms to give a longitudinal traction, pulling the Stockinette straps to provide a bending moment at the apex level, and stabilizing the pelvis and lower limb. These procedures are cumbersome to coordinate the manipulation endeavor and make 3D trunk scanning difficult.

**Objective:** The aims of the study were two-fold: 1) to apply a Torso Measurement Frame (TMF) for manipulating the trunk and correcting posture while scanning a 3D back contour to establish a treatment protocol; 2) to validate the feasibility of the TMF application and evaluate the outcomes of an Elongation Bending De-Rotation Brace (EBDB) in a short visit.

**Methods:** Two children with juvenile idiopathic scoliosis were retrospectively evaluated. The TMF is in an outpatient clinic setting, where the child stood still and grasped two vertical rods above the head. One hand was positioned on a rod higher than other tilting the trunk toward the convex side and elongating the concave side. An appropriately sized Stockinette strap at the apex level was connected with Q'Straint track restraint system and controlled by the physician to provide a translational and de-rotation force and to correct the curve in the coronal and transversal plane (Figure 1a). While the patient was in the corrected position, a hand-held scanner registered the 3D torso, then the EBDB was designed and manufactured using CAD/CAM technology (Figure 1b).

**Results and Discussion:** Age at start of EBDB was 9 years and 8 months for the 1<sup>st</sup> child and 6 years and 4 months for the 2<sup>nd</sup> one. They cooperated well with manipulation using the TMF and had a good compliance with wearing brace for 18 hours daily. The major Cobb angle was reduced ranging from 12° to 18° in 3 months follow-up (Figure 1c and 1d).

**Conclusion and Significance:** The TMF is a reliable and user-friendly tool that provides measurable forces to correct spinal curvature and leads to custom braces in older children with scoliosis.

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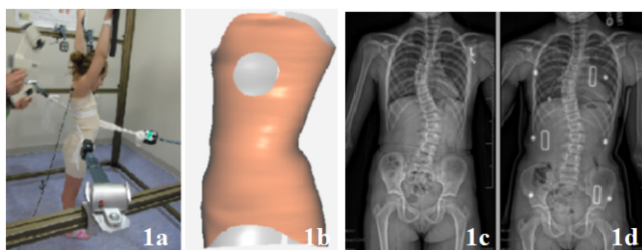


Figure 1a: Positioning, correction, and scanning for a 6-year-old girl; 1b: design for EBDB; 1c and 1d: The thoracic and lumbar Cobb angle were reduced 12°, and 18° respectively between out of brace and in-brace.

## Modification of EBDB for EOS

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**Introduction:** Elongation-derotation-flexion (EDF) casting techniques have been the primary treatment of early-onset scoliosis (EOS). This technique aims to correct malformations secondary to improper spinal growth and potentially improve spinal deformity. Complications of this design include skin irritation and muscle atrophy of the patient as well as financial strain on caregivers due to frequent cast changes. Through similar methodology, an Elongation-bending-derotation-brace (EBDB) has been developed to allow for superior management of scoliosis while reducing known complications.

**Objective:** As a new design, modifications are necessary to cultivate the desired outcome. The aim of this study was to provide the limited experience with how to modify the current EBDB as well as improve the overall design of the EBDB using CAD technology.

**Methods:** When providing this orthosis, shape and fit of the device can alter the functionality. The EBDB is fabricated with a soft foam interface and low density modified polyethylene outer frame that must be trimmed and flared upon fitting to ensure appropriate lever arms for force application. Tools that are commonly used for these modifications include a 5-in-1 plastic cutter, jigsaw, Troutman (carver/sander) and a heat gun. The case study provided shows improvement of spinal curvature through usage of the EBDB in succession as well as revisions needed throughout the process.

**Results and Discussion:** A standard set of modifications now takes place following each orthosis delivery. Due to the traction placed on the patient when scanned, excess tissue that covered bony prominences is elongated and taut. The EBDB requires heat reliefs over the iliac crest and ASIS bilaterally (Figure 1a and 1b). This elongation also results in over-compression of the abdomen that often leads to regurgitation (Figure 1a). An abdominal cutout in the outer plastic frame allows reduced pressure due to the flexibility of the inner foam lining. A lateral window is trimmed out of the outer frame contralateral to the thoracic curvature to allow for rib excursion (Figure 1c). This feedback has been adopted into the modifications now incorporated in the CAD model.

**Conclusion and Significance:** Achieving the appropriate function from the EBDB required adjustments to the orthoses to ensure skin integrity and active muscle use while using corrective force application to reduce scoliosis curve magnitude. Following modification of the EBDB, not only has improved scoliosis correction been achieved but coronal and sagittal plane balance over the pelvis has been observed. Increased quality of life for the patient and caregiver(s) has also been expressed when using this design.

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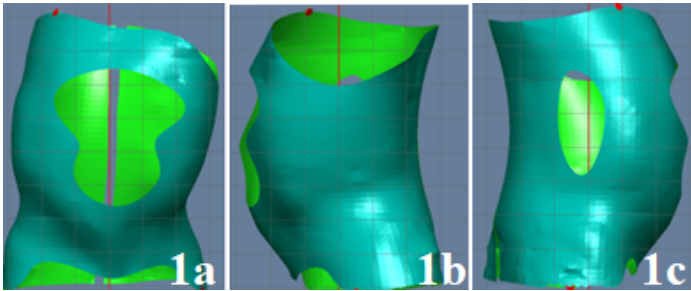


Figure 1a: Iliac crest relief and an abdominal cutout; 1b: ASIS relief; 1c: a lateral window

## Reducing the fixed, angular kyphosis in the Achondroplasia patient

EJ MALONEY

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**Introduction:** Achondroplasia is a very rare genetic condition with fewer than 20,000 US cases per year.

**Objectives:** Present the ideal type of custom TLSO to reduce further sagittal deformities by reducing the anterior load on the Angular vertebrae and return it to a more normalized alignment.

**Methods:** Custom 3-point pressure system TLSO with liner and pressure pads.

**Results and Discussion:** Reduced kyphotic angle by 10 degrees with her first brace after additional apex bolster pads.

**Conclusion and Significance:** Nearly all infants with achondroplasia develop a thoracic junction kyphosis during the first year of life.[1] Of those only 10% will get progressive kyphosis. With this development of wedging, there indicates a risk of persistence or progression of the kyphosis which can lead to a fixed, angular deformity. With early onset detection and placed in a properly fitted and functioning custom TLSO, the risk of a fixed Angular Kyphosis can be avoided, and the sagittal kyphosis angle can be stabilized and normalized thus reducing long term affects.

### References

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Comparisons of trunk rotations and deviations during walking  
before and after PSSE

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**Introduction:** Patients with Adolescent Idiopathic Scoliosis (AIS) present with a variety of spinal alignment deviations. It has been clinically observed that these patients benefit from PSSE to improve aesthetics of their posture. It is unclear if this correlates with improvements in trunk alignment during dynamic tasks.

**Objective:** The purpose of this study was to determine if there are changes in trunk alignment during dynamic gait and evaluate whether this can be improved with PSSE.

**Methods:** 6 subjects with AIS were recruited for this study. None of the subjects had previously been involved in PSSE as a treatment. Each subject was evaluated pre- and post- PSSE using Diers formetric system to measure several elements of trunk alignment. They were analyzed during the following phases of gait: loading, mid-stance, pre-swing, and end-swing. The same physiotherapist treated the subjects and was blinded by what was being measured. The subjects were taken through a series of PSSE specific to their curve and ability to perform with adequate postural correction.

**Results and Discussion:** Following 12 weeks of PSSE, there were moderate improvements in several phases of the gait cycle (see table 1). Reductions in the coronal imbalance was found across the loading, mid-stance and pre-swing. Pelvic obliquity was improved, though only after the mid-stance phase of gait. Pelvic rotation was also improved at loading, and swing. Pelvic inclination was reduced at pre-swing. All other variables had no significant improvement throughout the gait cycle.

**Conclusion and Significance:** In patients with Adolescent Idiopathic Scoliosis, PSSE enables improved dynamic posture in some phases of the gait cycle, but not all.

Table 1. Comparison of trunk deviation and rotation and pelvic motions before and after PSSE during walking (n=6, % changes)

Parameters	Loading			Mid-stance		
	Pre-PT Mean±SD	Post-PT Mean±SD	% Change	Pre-PT Mean±SD	Post-PT Mean±SD	% Change
Coronal Imbalance VP - DM	-11.66±15.55	-3.34±22.83	-71.36	-12.82±13.35	-1.72±25.07	-86.58
Vertebral Rotation (+) max (°)	3.49±3.29	4.86±2.90	39.26			
Pelvic Obliquity (°)	-1.08±3.75	-1.48±1.36	37.04			
Pelvic Rotation (°)	-2.54±4.91	0.36±3.01	-114.17	0.02±3.86	4.34±3.01	21600
Parameters	Pre-swing			End Swing		
	Pre-PT Mean±SD	Post-PT Mean±SD	% Change	Pre-PT Mean±SD	Post-PT Mean±SD	% Change
Coronal Imbalance VP - DM	-10.92±12.43	-5.32±18.64	-51.28	-8.34±8.44	-13.56±12.66	62.59
Apex Deviation VP - DM max				8.86±16.45	2.52±24.64	-71.56
Pelvic Obliquity (°)	-0.92±4.28	0.32±1.59	-134.78	-1.34±5.50	1.48±3.34	-210.45
Pelvic Inclination Dimples (°)	34.76±25.87	21.10±5.18	-39.3			
Pelvic Rotation (°)	-0.40±3.04	2.6±3.06	115.4	-4.90±3.37	-1.70±2.18	-65.31

Note: Coronal Imbalance and Apex Deviation are in mm.

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## Cosmetic changes in patients following a Schroth exercise regime: a two year follow-up

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**Introduction:** The Schroth method is one of the non-surgical options available to patients exhibiting mild to moderate scoliosis. This technique employs customised exercises with the aims of restoring muscular symmetry, postural alignment and awareness coupled with introducing new breathing strategies. In some cases, bracing may also be a part of the treatment. This depends on the patient's age, bone maturity and degree of curvature. This treatment option requires a long-term commitment. Although previous reports have shown the clinical effectiveness of this option, there is a lack of structured studies on the cosmetic changes.

**Objectives:** The primary objective of our longitudinal study over the past two years has been to investigate the relationship between Cobb angle(s), curve type (King), clinic reports, clinical images, ISST-12-15 II-Schroth scoliosis classification and back shape data with the goal to develop, test and to validate derived cosmetic deformity metrics.

**Methods:** After necessary ethical approval, we captured the tri-dimensional topography of 145 patient presentations at Schroth camps in Serbia, Bulgaria and Romania. After recording anthropometric and Cobb angle data with Schroth and radiological curve type classifications, we recorded the back surface shape using a commercially available depth camera (Kinect™ One, Microsoft Corporation) and analysed the resultant point cloud using contemporary computer vision algorithms. We compared the patient data with that obtained from a group of 23 typically developed adolescents and adults not exhibiting any musculoskeletal disease to test the efficacy of proposed surface asymmetry metrics, correlating them with radiological measures and classifications amongst the patient group.

**Results and Discussion:** Our results indicate clear differences in the surface topography of the back between the typically developed subjects and the patient cohort. This has provided a useful first step to develop a better understanding of how these measures could be applied clinically. As a part of this pilot investigation, we present five cases (four AIS and one congenital case) measured over a two-year period to investigate changes in the derived surface imagery and metrics against radiological measures and clinical reports over time.

**Conclusion and Significance:** Reported results on the longitudinal trends observed amongst these AIS patients attending multiple Schroth camps will help design further structured studies with the aim of establishing metrics that can contribute to effective clinical management.

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# Chapter 16

## Abstracts for Surgical Intervention

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## Short term results of selective thoracic instrumentation in Lenke 3C idiopathic scoliosis

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**Introduction:** Classification of idiopathic scoliosis (IS) according to Lenke was introduced to determine the extent of instrumentation and fusion. There is an interest in selective surgery for double structural curvatures.

**Objectives:** Assessment of Lenke 3C IS selectively instrumented in the thoracic spine in order to study the coronal, sagittal and transverse plane change observed within the lumbar non instrumented spine.

**Materials:** The study involved 14 patients, aged 12-17 years, with Lenke 3C IS operated through 2013-2018. The follow-up was 22 months (range 5 to 52) in 9 patients. The mean thoracic Cobb was 70 degrees and the lumbar Cobb was 53. In 9 patients the Cobb ratio (Cobb thoracic/Cobb lumbar) was above 1.2 and in 5 patients below 1.2. The lower instrumented vertebra was the stable vertebra in 9 patients, one level below in 2 patients and 1 level above in 3 patients.

**Methods:** Cobb angle of the thoracic and lumbar spine, clavicle angle, C7 spine imbalance, distal junctional kyphosis (DJK), sagittal vertical axis (SVA) and Raimondi rotation of the apical lumbar vertebra (AVR) were examined. The parameters were assessed immediately before, one week after surgery and at follow-up.

**Results and Discussion:** The mean thoracic Cobb correction was 45% after instrumentation and 42% at follow-up, while the lumbar Cobb correction was 33% and 26%, respectively. After surgery, the clavicle angle was below 4 degrees in all patients and maintained at follow-up except for one patient (4.2 degrees). No C7 spine imbalance was noted after surgery except for two patients who shifted 3.6 and 3.7 cm to the left. No DJK was observed after surgery nor at follow-up. Prior to surgery, all patients presented SVA values within the normal limits (+/- 5cm) while after surgery, the SVA was -7.7cm in 2 patients. The mean Raimondi lumbar AVR was 25 degrees before surgery, 23 after surgery and 26 at follow-up.

**Conclusion and Significance:** The spontaneous correction of the lumbar curvature after selective thoracic instrumentation of Lenke 3C IS comprised the Cobb angle but not apical vertebral rotation. No DJK was noted in any patient at follow-up. Further observation is needed to assess the rationale of selective fusion in Lenke 3C idiopathic scoliosis.

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## Efficacy of posterior only approach for complex iatrogenic flat back

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**Introduction:** Lumbar surgical instrumentation with pedicle screws at more than 4 levels for degenerative pathologies, may result in flat back syndrome. Revision surgery may be performed with different approaches.

**Objective:** We describe our experience in revision surgery with a single posterior approach.

**Methods:** Inclusion criteria: symptomatic patients with lumbar hypolordosis (lumbar lordosis (LL) inferior to Pelvic Incidence (PI)), previously treated with pedicle screw instrumentation for lumbar degenerative disease at 4 levels at least, revision surgery performed between 2011 and 2016, minimum FU 24 months. A total of 22 patients were identified (18 F, 4 M), mean age was 67 years (min 45, max 77), mean follow up was 28.2 months (min 24, max 48). All secondary operations were performed by a single posterior approach, by removing previous lumbar instrumentation and performing multi-level posterior column osteotomies and multiple interbody cages. Radiographic calculations included lumbar LL, PI, sagittal imbalance (SI). Complications and clinical evaluation with Oswestry and VAS questionnaires were also performed.

**Results and Discussion:** Mean lordosis improved from 18° (min. 3°, max 38°) to 57° (min. 42, max 72°). Sagittal imbalance improved from +75 mm (min 40, max 150) to 10mm (min -5, max 20). 9 neurological complications (40,9%), of whom two major (9.1%) and 7 minor (31.8%) occurred in 6 patients. 6 post-operative mechanical complications (27.7%) that required revision surgery occurred in 5 patients. Oswestry and VAS questionnaires showed statistically significant improved outcome at final follow up.

**Conclusion and Significance:** Posterior revision surgery for lumbar instrumentations with post-operative flat back, is a safe and efficient procedure, capable of restoring satisfactory lumbar lordosis thanks to a variety of posterior column osteotomies and use of interbody cages.



## A new surgical method for combining segmental and en block direct vertebral body rotation

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**Introduction:** Direct vertebral body rotation (DVBR) may be performed either by segmental or en bloc maneuvers.

**Objective:** In this study we describe a detailed surgical technique that combines both DVBR methods during the same surgical procedure.

**Methods:** Surgical technique: uniplanar pedicle screws are placed at all or nearly all levels (instrumentation density above 90%, at least 1 pedicle screw per level), screw extensors are afterwards placed on both sides and sequential segmental DVBR is performed from the neutral level towards the apex of the curve, convex extensors are blocked in the desired segmentally rotated position and are kept in situ during all remaining corrective maneuvers. Corrective maneuvers in translation, CD rod rotation and en block DVBR are then performed. Concave screws are blocked and all extensors are removed. Convex rod is afterwards placed in a Cantilever fashion in order to enhance rib hump reduction. In all cases, we used cobalt chrome rods contoured in a differential manner with hyperkyphotic concave rod and hypokyphotic convex one. A total of 35 patients with AIS treated surgically with combined segmental and en block DVBR. Mean age was 15.7 years (min 12, max 18), 23 patients were female and 12 were male. Mean major curve Cobb angle was 64.3° (min 40°, max 88°), mean follow up was 2,3 years (min 2 year, max 3 years). All types of Lenke curves were included. Scoliosis correction was measured on pre and post-operative standing x-rays, apical vertebral rotation was measured with CT scan. Clinical results were measured using standard rib hump scoliometer.

**Results and Discussion:** Main curve was corrected from 64.3° to 16.7°, thoracic kyphosis was corrected from a mean 3.6° to a mean 23.2°. Apical vertebral rotation improvement was statistically significant: pre-op RAsag 23.6°, post-op RAsag 8.4°. 0. Rib hump improved significantly from a mean 12.7° to a mean 3.6° at final follow up.

**Conclusion and Significance:** The described surgical technique of combined SD and EBD can enhance overall DVBR and therefore provide satisfactory axial rotation and overall scoliosis correction.

**The clinical significance of tether breakages in anterior vertebral body growth modulation: a two-year post-operative analysis**

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**Introduction:** Anterior vertebral body growth modulation (AVBGM) is a technique aimed at treating skeletally immature patients with progressive idiopathic scoliosis (IS). Early results are promising, but tether breaking is a concern. Whether this subgroup has a different post-op evolution may allow us to understand and predict failures.

**Objective:** We aim to evaluate the first two post-op years in patients who have developed tether failures compared with patients without other major complications.

**Methods:** A retrospective review of a prospectively maintained database of IS patients operated with AVBGM from 2013 to 2019 was performed. Inclusion criteria were patients having at least two year radiologic and quality of life SRS-30 questionnaires completed. Patients diagnosed with tether failures based on radiological data were included. Patients excluded from this study was any diagnosis other than IS and major complications other than tether failure. Wilcoxon Rank-sum test was used to compare results between patients with and without tether failure.

**Results and Discussion:** Sixty-two patients were identified. Twenty-two patients were identified with tether failures. One patient with tether failure required revision surgery and was excluded from this study. Including this patient, a total of 8 patients were excluded. 21 patients with tether failures and 33 patients with minor or no complications were analyzed. Average age for index surgery was 11.9 and 12 for each respective group. No significant differences ( $p > 0.05$ ) were seen for maximum Cobb angles, kyphosis or lordosis between both groups. Significant differences ( $p < 0.05$ ) were noted in SRS-30 quality of life pre-op scores between the two groups, but were not found at 2 years post-op.

**Conclusion and Significance:** Patients who develop tether failures may have similar post-op outcomes than patients with no post-operative complications within the first two post-operative years. Further analysis is needed to define the natural evolution of tether failures. Patients who develop tether failures may have similar post-operative radiological and quality of life scores to patients without any complications. The significance of tether failures needs to be further studied.

Table 1. Radiological and SRS-30 quality of life outcome scores

	Minor or no Complications (N=33)	Tether Failure (N=21)	P-values
Pre-op Cobb Angle	48.1 ± 8.3	49.8 ± 9.3	0.39
Cobb Angle 2-year Follow-up	26.6 ± 9.3	31.3 ± 10.1	0.12
Pre-op Kyphosis	17.8 ± 12.0	18.0 ± 9.4	0.74
Kyphosis 2-year Follow-up	18.2 ± 12.5	14.7 ± 9.9	0.30
Pre-op Lordosis	57.3 ± 9.8	54.4 ± 9.0	0.25
Lordosis 2-year follow-up	58.5 ± 12.5	57.6 ± 7.2	0.61
SRS-30 Total Score pre-op	3.97 ± 0.72	4.21 ± 0.49	0.03
SRS-30 Total score 2-year Follow-up	4.24 ± 0.35	4.18 ± 0.36	0.51

## Innovative technique with magnetic growing rod for treatment of severe scoliosis

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**Introduction:** Severe scoliosis correction has always represented a challenging surgical procedure with high risk of neurological complications.

**Objective:** To evaluate the efficacy, safety and limits of a new surgical technique for the management of severe scoliosis. It consists in applying a temporary magnetic growing rod to the curve's concavity, that can be used as a gradual distraction and staged correction before the definitive surgery.

**Methods:** Twenty patients with severe scoliosis treated from 2014 to 2018 were retrospectively reviewed. They underwent implant of a temporary magnetic growing rod, followed by definitive fusion after a 3 week period. The mean age of the patients was 15.5 yrs (12-26), 15 females and 5 males with severe scoliosis, among which 14 were idiopathic, 3 syndromic (1 sd. Noonan, 1 sd. Marfan and 1 NF1), 1 thoracogenic, 2 were the consequences of tumors (intramedullary ependymoma and neuroblastoma). In the series, 4 cases presented with spinal cord malformations before undergoing surgery. Patients had a pre-operative Cobb Angle of 114.3° on average (range 91 ° -137 °) and 71.8 ° of kyphosis (range 15 ° -126 °). During the three-week period between surgeries, we performed a daily lengthening of the magnetic rod (about 2-3mm every day).

**Results and Discussion:** Thoracic main curve improved from a mean pre-op 114.3 ° Cobb (range 91°-137°) to a mean post-op 77.2° Cobb after the implant of a temporary magnetic growing rod (range 48° - 103°). Mean correction after final surgery was 56.2° (range 31° -82°). We also evaluated the lengthening of the magnetic rod (14,4mm on average) and correlated it to BMI, age, gender, Cobb Angle and kyphosis angle. BMI had not a significant correlation with lengthening of the MAGEC ( $P=0,22$ ). Results did not differ based on gender ( $p = 0.12$ ). Kyphosis, age and Cobb Angle are significantly correlated with the lengthening (in order  $p=0,002$ ;  $p=0,02$ ;  $p=0,036$ ). No severe neurological complications were observed.

**Conclusion and Significance:** The temporary magnetic rod is a safe and useful method for temporary distraction of the spine in severe idiopathic scoliosis.

## Does the hybrid construct of transversal hook and pedicle screw at the upper instrumented vertebra provides sufficient correction? - early results

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**Introduction:** Although the pedical screw only constructs (PSOC) are the most commonly used in idiopathic scoliosis (IS) surgical treatment, there are studies suggesting that hybrid constructs with hooks at the upper instrumented vertebra (UIV) may be beneficial for avoiding proximal junctional kyphosis. What is more, there happen surgical situations when safe implantation of the proximal pedicle screw is very demanding or impossible. The compromise solution between PSOC or double hooks construct may be instrumentation of the UIV with the one pedicle screw and one transversal hook. However, this solution brings question about the quality of IS correction.

**Objective:** To determine if the hybrid combination (HC) of transversal hook and pedical screw at the upper instrumented vertebra provide correction of the IS curvatures comparable with pedicle screw only construct.

**Methods:** Fifty-seven patients with the thoracic major curvature (Lenke 1 or Lenke 3), 17 males and 40 females, mean age  $14.6 \pm 1.9$ , underwent surgical correction of IS. In 26 patients HC and in 31 patients PSOC were used. HC consisted of pedicle screw at the concave side of thoracic curvature and transversal hook at the convex side of thoracic curvature. Standing AP and lateral with maintained horizontal gaze (chin-brow vertical angle CBVA  $\leq 15^\circ$ ) X-rays were analyzed. The measurements concerning curves magnitude, proximal thoracic and cervical spine sagittal alignment were performed prior to and one week after thoracic curve surgery as follow: Cobb angle, T1-T4 kyphosis, T1 slope, thoracic inlet angle (TIA), neck tilt (NT), cranial tilt, cervical sagittal vertical axis (cSVA), C2-C7 lordosis, CBVA. Differences between post-surgical and pre-surgical results were calculated and compared between groups with 0.05 as a statistically significant threshold.

**Results and Discussion:** The groups before surgery were matched for age, gender, curves magnitude and sagittal alignment of proximal thoracic spine (Th1-Th4 kyphosis), thoracic inlet (TIA, T1 slope, NT) and cervical spine (cranial tilt, cSVA, C2-C7 lordosis), see Table 1.

In the early post-surgical evaluation, the correction was comparable in proximal thoracic, main thoracic and lumbar curvatures.

The amount of correction of the sagittal alignment parameters of the proximal thoracic spine, thoracic inlet and cervical spine did not reveal difference between PSOC versus HC.

**Conclusion and Significance:** The hybrid construct consisting of proximal convex transversal hook combined with pedical screw at the upper instrumented vertebra did not affect the correction of thoracic idiopathic scoliosis.

Table 1. Correction of idiopathic scoliosis patients treated with pedicle screws only construct versus hybrid combination of transversal hook and pedical screw at the upper instrumented vertebra

	PSOC (N =31)		HC (N=26)		P
	Mean±SD	Min - max	Mean±SD	Min - max	
Age (y.o.)	14.3±2.0	11-18	15.0±1.8	12-19	0.18581
Gender (F:M)	21:10		19:07		0.77452
Lenke 1:Lenke 3	18:13		13:13		0.60042
<b>Pre-surgical results</b>					
Proximal thoracic Cobb angle (°)	31.9±8.1	(14-44)	30.6±8.5	(16-44)	0.40023
Main thoracic Cobb angle (°)	71.8±13.2	(48-106)	70.6±11.6	(52-105)	0.72651
Lumbar Cobb angle (°)	47.6±17.7	(18-80)	44.2±18.4	(21-105)	0.39143
Th1- th4 kyphosis (°)	9.0±5.1	(0-21)	8.7±4.9	(-1-16)	0.84061
T1 slope (°)	12.7±7.1	(-2-25)	12.7±7.5	(0-26)	0.76651
TIA (°)	55.1±9.6	(37-80)	53.3±8.9	(32-71)	0.68791
Neck tilt (°)	42.4±9.3	(30-64)	40.5±9.4	(24-57)	0.45721
Cranial tilt (°)	6.7±5.9	(-2-25)	5.9±5.1	(-1-17)	0.54211
cSVA (mm)	18.1±11.9	(-9-44)	15.1±13.9	(-36-35)	0.60263
C2-C7 lordosis (°)	-1.8±11.6	(-29-20)	-2.5±12.9	(-32-17)	0.81441
<b>Post-surgical differences in results</b>					
ΔProximal thoracic Cobb angle (°)	11.0±6.6	(1-29)	12.4±6.7	(2-27)	0.44831
ΔMain thoracic Cobb angle (°)	41.4±10.7	(21-65)	40.3±10.2	(17-63)	0.43233
ΔLumbar Cobb angle (°)	22.5±10.9	(7-54)	26.4±12.9	(11-52)	0.35031
ΔTh1- th4 kyphosis (°)	-0.6±5.3	(-14-11)	-0.7±5.1	(-10-8)	0.77931
ΔT1 slope (°)	1.2±6.3	(-18-11)	2.5±7.2	(-12-19)	0.50271
ΔNeck tilt (°)	-2.5±6.9	(-18-8)	-1.4±5.8	(-13-8)	0.52841
ΔCranial tilt (°)	-0.3±4.8	(-15-9)	-0.2±4.8	(-9-10)	0.92981
ΔcSVA (mm)	-4.6±12.9	(-45-21)	1.9±15.4	(-18-54)	0.08941
ΔC2-C7 lordosis (°)	6.5±11.5	(-17-28)	7.4±12.3	(-13-36)	0.79821

<sup>1</sup> t – Student, <sup>2</sup> Chi<sup>2</sup>, <sup>3</sup> U – Mann – Whitney; p<0.05 **bolded**; thoracic inlet angle (TIA); cervical sagittal vertical axis (cSVA); (HC) hybrid combination of transversal hook and pedical screw at the upper instrumented vertebra; pedical screw only constructs (PSOC); Δ –difference between pre-surgical versus post-surgical results

## Cervical spine sagittal alignment following surgical correction of Lenke type 1 idiopathic scoliosis – early results

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**Introduction:** The cervical spine alignment in patients with thoracic idiopathic scoliosis (IS) very often is impaired due to the fact that change in one spine segment can interfere with adjacent segments. Thus, surgical correction of the thoracic spine may impact on the cervical one.

**Objective:** The aim of the study was to determine the immediate impact of thoracic curvature correction on the cervical spine sagittal alignment.

**Methods:** Thirty-one patients, 10 males and 21 females, mean age 14.6±1.8yo, all presenting single thoracic scoliosis (Lenke 1), underwent surgical correction. Upper instrumented vertebra (UIV) was: Th2 N=4, Th3 N=6, Th4 N=6, Th5 N=9 and Th6 N=6. Standing AP and lateral with maintained horizontal gaze (chin-brow vertical angle ≤15°) X-rays were analyzed. The following measurements were performed prior to and one week after surgery: chin-brow vertical angle (CBVA), C0-C2 lordosis, C2-C7 lordosis, cervical sagittal vertical axis (cSVA), cranial tilt, neck tilt, thoracic inlet angle (TIA), T1 slope, T1-T12 kyphosis, L1-S1 lordosis, sagittal vertical axis, pelvic tilt, sacral slope, pelvic incidence and Cobb angle. Cervical alignment between prior to and after surgery was compared using paired t-test or Wilcoxon test. Correlations were established with Pearson coefficient. The patients were analyzed separately according to the UIV: T2-T4 (N=16) versus T5-T6 (N=15) and compared with t-test and Mann-Whitney test.

**Results and Discussion:** After surgical treatment of the main thoracic curvature a partial spontaneous correction of the thoracic proximal and the lumbar non-structural curvature was observed. Significant decrease of lumbar lordosis was noted, accompanied by a not significant increase of thoracic kyphosis.

The neck tilt decreased significantly and T1 slope increased (not significant). Significant increase of the distal cervical lordosis (C2-C7) was observed while the C0-C2 lordosis did not change. Cranial tilt and cSVA decreased (not significant).

The increase of C2-C7 lordosis negatively correlated with cSVA ( $r=-0.4$ ,  $p=0.0254$ ) and cranial tilt ( $r=-0.36$ ,  $p=0.0433$ ), respectively. The increase of cervical lordosis was significantly higher in patients with UIV T2-T4 versus UIV T5-T6,  $p=0.0362$ .

**Conclusions and Significance:** Slight but significant of the cervical sagittal alignment was noted after thoracic curvature correction in patients with idiopathic scoliosis Lenke type 1. The alignment changed in the distal cervical segments and the thoracic inlet area but not in the sub-occipital area. The increase of cervical lordosis correlated with decrease of cranial tilt and cSVA and may be associated with higher level of instrumentation.

Table 1. Cervical spine sagittal alignment after surgical correction of Lenke type 1 IS

	Pre-surgical		Post-surgical		P
	Mean±SD	Min - max	Mean±SD	Min - max	
Proximal thoracic Cobb angle (°)	34.7±7.6	(21-44)	20.7±6.3	(12-28)	<b>0.0001</b> <sup>2</sup>
Main thoracic Cobb angle (°)	69.9±9.8	(52-95)	26.9±7.9	(16-50)	<b>0.0001</b> <sup>1</sup>
Lumbar Cobb angle (°)	32.9±7.4	(18-46)	13.7±7.5	(0-29)	<b>0.0001</b> <sup>2</sup>
CBVA (°)	6.4±5.7	(-11-15)	5.7±5.5	(-5-15)	0.5419 <sup>1</sup>
C0-C2 angle (°)	28.1±7.8	(11-43)	27.8±7.3	(12-42)	0.5426 <sup>1</sup>
C2-C7 lordosis (°)	-1.9±12.1	(-29-18)	2.8±12.9	(-20-22)	<b>0.0429</b> <sup>1</sup>
cSVA (mm)	21.1±10.9	(-9-44)	18.0±13.1	(-31-42)	0.1710 <sup>1</sup>
Cranial tilt (°)	8.2±5.1	(-1-25)	7.6±6.6	(0-20)	0.2810 <sup>2</sup>
Neck tilt (°)	41.1±10.2	(26-64)	38.4±6.6	(24-49)	<b>0.0329</b> <sup>1</sup>
TIA (°)	54.5±9.9	(34-80)	53.7±9.0	(34-78)	0.1928 <sup>1</sup>
T1 slope (°)	13.5±7.7	(-2-26)	15.1±7.4	(-3-29)	0.1384 <sup>1</sup>
T1-T12 kyphosis (°)	26.7±10.7	(2-48)	28.3±9.9	(6-44)	0.3285 <sup>1</sup>
L1-S1 lordosis (°)	51.7±11.8	(25-72)	47.4±10.4	(30-70)	<b>0.0047</b> <sup>1</sup>
SVA (mm)	-4.1±29.8	(-68-55)	-6.8±22.0	(-56-36)	0.8788 <sup>1</sup>
Pelvic incidence (°)	47.4±11.2	(22.8-72)	47.1±10.9	(24-71)	0.3777 <sup>1</sup>
Sacral slope (°)	38.7±9.6	(9-55)	36.7±8.1	(21-52)	0.6543 <sup>1</sup>
Pelvic tilt (°)	10.1±8.8	(-6-45)	10.5±6.2	(0-27)	0.1682 <sup>2</sup>

<sup>1</sup> paired t – test, <sup>2</sup> Wilcoxon test; p<0.05 **bolded**; thoracic inlet angle (TIA); cervical sagittal vertical axis (cSVA); chin-brow vertical angle (CBVA); sagittal vertical axis (SVA),

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# Chapter 17

## Abstracts for Functional Outcomes

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## A useful survey to help understand bracing and pre-surgical planning in children with scoliosis

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**Introduction:** We have organized educational meetings or workshops for children with scoliosis who wear braces or who begin the surgical treatment process. This has become a key component in our clinical practice for over 20 years.

**Objective:** This survey was undertaken to investigate: 1) if children's parents understand bracing or spinal surgical care and impacts of these treatments on children's daily life; 2) which type of brace or conservative treatment is selected most frequently; 3) which group of children shows more concern with appearances.

**Methods:** Data was collected in a questionnaire that was given out after workshops that are put on for the patients. On the questionnaire there are no identifiers making this anonymous. 28 (bracing group) were surveyed after the pre-brace workshop and 13 (pre-surgical group) were surveyed in the pre-surgical workshop. After the questionnaires are filled out, answers were tallied in an excel sheet. A descriptive analysis and a Fisher's Exact test were performed.

**Results and Discussion:** All patients and their parents found the workshops helpful. The bracing questionnaire consisted of 5 domains: How helpful was the forum (excellent - 71.43%), Quality of Life (None & All – both 28.57%), additional information wanted (No – 100%), Type of Brace worn (Boston – 82.14%), and Time per day (> 16 hrs – 67.86%). The pre-surgery questionnaire had 4 domains: How helpful was the forum (excellent – 61.54%), Quality of Life (Appearance – 61.54%), Additional info wanted (No – 92.31%), and if there was any treatment beforehand (Bracing – 38.46%). The quality of life at school was affected in both bracing group (21%) and surgical group (7.7%). There was no difference at overall quality of life ( $P>0.05$ ). Analysis showed that those who go into surgery have more concerns about their appearances (61.54%) than those who choose the brace (25.00%) ( $P<0.05$ ).

**Conclusion and Significance:** Our survey suggests that the educational workshop for children with scoliosis is very important to understand pros and cons in bracing or surgery, and further prepare for encountered problems in advance, which may result in better clinical outcomes.

**Acknowledgement:** We would like to thank Mr. Ellis, BS and Dr. Tarima for the data analysis, as well as Susan Soderberg, RN and Sarah Henner, RN for their assistance in conducting these workshops.

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## Factors affecting satisfaction of pediatric posterior spinal fusion patients

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**Introduction:** Post-operative pain is a significant concern for patients undergoing Posterior Spinal Fusion (PSF) for scoliosis, and their parents (Chan et al., 2017). Patient Controlled Analgesia (PCA) allows patients to administer pain medication on an as-needed basis for post-surgical pain, with PSFs being one of the most common surgeries for which PCAs are utilized. New PCA pumps can indicate whether or not a patient will receive medication when they push the PCA button via a green light. For this randomized controlled trial, we included 2-arms: 1) a Light arm (a green light indicates status of the lockout period) and a Control arm (no cues to lockout period status).

**Objective:** Determine whether satisfaction rates differ between groups based on gender, age and light/control condition.

**Methods:** As part of a larger study, 51 patients ( $Age = 14.12 \pm 1.95$ ; 74.5% female) undergoing PSF were asked about their satisfaction with the PCA pump, pain management experience, worry about getting enough pain medicine, and ease of knowing the lockout period was over. All questions were rated on a 0 – 10 scale, with 0 = “very dissatisfied” or “not at all worried,” 10 = “very satisfied” or “very worried.”

**Results and Discussion:** Results indicated that male users ( $M = 8.55$ ,  $SD = 1.30$ ) of the PCA pump were more satisfied with the experience than female users ( $M = 6.70$ ,  $SD = 2.52$ ) ( $p = .003$ ). Satisfaction with the PCA pump experience did not differ between children ( $\leq 12$  years) and adolescents ( $\geq 13$  years). However, adolescents ( $M = 4.59$ ,  $SD = 2.78$ ) were significantly more worried about getting enough pain medication than children ( $M = 1.89$ ,  $SD = 2.89$ ) ( $p = .014$ ). Satisfaction with PCA pump experience did not differ between Light/Control groups. However, difficulty in knowing when the lockout period ended was significantly higher in those in the control group ( $M = 5.70$ ,  $SD = 3.68$ ) than for those in the light group ( $M = 8.69$ ,  $SD = 2.89$ ) ( $p > .005$ ).

**Conclusion and Significance:** Multiple factors may influence a patient's satisfaction with pain management as well with as the overall experience after PSF surgery. This study shows that gender, age, and technology are important factors to consider. It is critical that we continue to find ways to improve the experience for patients undergoing PSF for scoliosis. Of particular importance, future studies should determine ways to increase satisfaction for female patients, and ways to reduce adolescents' concern about getting enough pain medicine.

**Reference:** [1] Chan P, Skaggs DL, Sanders AE, et al. Pain is the greatest preoperative concern for patients and parents before posterior spinal fusion for adolescent idiopathic scoliosis. *SPINE*. 2017; 42(21): E1245-E1250.

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## Polish adaptation of the Italian spine youth quality of life questionnaire

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**Introduction:** Negative impact of spinal deformities on health-related quality of life (QoL) is well known. The SRS-22 questionnaire is commonly used for the assessment of the QoL in children and adolescents with idiopathic scoliosis (IS). However, it was originally developed for surgically treated patients so it demonstrates high ceiling effect in non-surgical care. The Italian Spine Youth Quality-of-Life Questionnaire (ISYQOL) was shown to be appropriate in adolescents with IS or Scheuermann Juvenile Kyphosis (SJK) treated non-surgically.

**Objective:** The aim of the study was to carry on the process of cultural adaptation of the Italian Spine Youth Quality of Life ISYQOL Questionnaire into Polish.

**Methods:** Thirty-four adolescents with IS and two with SJK were enrolled, 31 girls and 5 boys, mean age 14.3 years ( $\pm 1.8$ ), mean Cobb angle 30.1 degree ( $\pm 10.1$ ), range 12 to 59. All patients have been wearing a corrective TLSO brace with an average duration of 2.2 years ( $\pm 1.7$ ). The Institutional Review Board approved the study.

The process of cross-cultural adaptation of the ISYQOL Questionnaire was performed in accordance with the guidelines set up by the International Quality of Life Assessment (IQOLA) Project, including the following steps: (1) forward translation, (2) expert panel back-translation, (3) pre-testing and cognitive interviewing, and (4) development of final version.

The reliability (internal consistency, test-retest reliability), floor, and ceiling effects of the Polish version of the ISYQOL were calculated. Internal consistency was assessed using the Cronbach alpha coefficient. Test-retest reliability was evaluated using Spearman correlation coefficient.

**Results and Discussions:** The Polish version of the questionnaire was developed and tested. The internal consistency was satisfactory: Cronbach alpha coefficient was 0.8. Test-retest study revealed high reliability with the Spearman correlation coefficient value of 0.97. There was neither floor nor ceiling effect for the ISYQOL overall score.

**Conclusion and Significance:** Polish version of the ISYQOL is reliable and can be used in adolescents with spinal deformity.

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## Recommendations of a complex care perioperative program for children with medical complexity

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**Introduction:** Children with medical complexity (CMC) have high rates of postoperative complications. To mitigate this risk, the Complex Care Program (CCP) offers preoperative assessments before orthopedic procedures for CMC, regardless of enrollment in the CCP. The assessment recommendations are directed at improving surgical readiness prior to the procedure and facilitating medical management postoperatively. The CCP distributes the preoperative assessment to the medical teams involved with the child's care (PICU, hospitalist, and orthopedic teams), and follows postoperatively as a consulting team.

**Objective:** Describe the recommendations of a CCP Perioperative Program prior to orthopedic procedures for CMC.

**Methods:** Retrospective chart review of all orthopedic CCP perioperative visits over three years (2017-2019). Recorded child's demographic information, diagnosis associated with the orthopedic problem and co-morbidities, procedure, and perioperative medical recommendations. Recommendations were categorized by organ system and patient frequency recorded.

**Results and Discussion:** Forty-six visits were examined, 28 female, 18 male, with an age range of 2-19 years. Diagnosis: central neuromuscular disease 38, peripheral neuromuscular disease 4, congenital bone deformities 3, and idiopathic scoliosis 1; also, all had a degree of developmental impairment, 25 were non-ambulatory, and 28 non-verbal. Medical comorbidities included cardiovascular disease, epilepsy, home respiratory support, and feeding tubes. Procedures performed: posterior spinal fusion 32, vertically expandable prosthetic titanium rib 4, osteotomies 6, and growing rod lengthening 4.

A GI system recommendation was made for all children, including bowel regimen, nutrition optimization, or management of enteral access (NG, G or J tube). There were also several pulmonary recommendations including post-extubation respiratory support and airway clearance. Several suggestions for patient comfort included pain team involvement, specific analgesic recommendations, a behavior plan, or behavioral medication administration. Neurology recommendations were made less often but included important topics such as seizure management and suggested route of antiepileptic drugs. Lastly, the CCP assisted with planning for home needs post discharge such as structural modifications, new equipment, or therapies.

**Conclusions and Significance:** Based on the number and variety of recommendations made, an opportunity exists to both improve surgical readiness and reduce postoperative complications in CMC. Future research will look at whether recommendations made were followed by the inpatient team. Next steps include examining the impact of CCP preoperative evaluations on postoperative outcomes including complications, family satisfaction, and length of stay.

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## Early physical therapy intervention in adolescent athlete with L5 Spondylolysis and grade 1 L5-S1 Spondylolisthesis: a case study

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**Introduction:** Spondylolysis and Spondylolisthesis can be a common cause of low back pain in the athletic adolescent population that can cause limitation of function within daily life and sport activity.

**Objective:** While most current research recommends prolonged periods of activity cessation and bracing initially, this case-study aims to assess the effectiveness and implications of early physical therapy intervention upon diagnosis and if expedited return to prior level of function and sport is feasible.

**Methods:** This case describes a high-level high school female athlete whose primary sport is volleyball. She was diagnosed with chronic Spondylolysis at L5 and Grade 1 Spondylolisthesis of L5-S1 with recommended treatment that included LSO for 23 hours per day, cessation of sport activity and initiation of physical therapy under Children's Wisconsin Spondylogenic Back Pain Protocol (10-12 week, 3 phase protocol).

**Results and Discussion:** The patient attended a total of 12 physical therapy sessions including the initial evaluation. She was able to wean out of her LSO between weeks 4-6 and progress through protocol to include trunk flexion, extension and rotational exercises. The patient was also able to progress her impact activities around week 6 via elliptical and running. From weeks 6-12 she was gradually re-introduced to volleyball activities with limitations in regards to time in practice and in effort with specific activities. By discharge from therapy the patient was pain free and participating fully in volleyball without her back brace. She was discharged with recommendations to continue her home exercise program at least 4 days per week and to do daily stretching for spine and lower extremities.

**Conclusion and Significance:** Early physical therapy intervention in addition to initial sport activity restriction, with or without bracing of the adolescent athlete may be effective to expedite return to prior level of function when compared to current research and treatment recommendations that limit most activity for at least 3 months and up to 6 months or more. This case-study could suggest more expeditious pain relief and return to full function in an earlier time frame (10-12 weeks). It may also suggest an ability to initiate awareness for overall spine health that could carryover from adolescence into adulthood to limit return of pain and functional limitations as the patient ages. While there are limitations as this is a one patient case-study, it does demonstrate effectiveness of early therapy intervention for Spondylolysis and Grade 1 Spondylolisthesis that allows for earlier pain-free return to prior level of function.

**References:** [1] Crawford C, Ledonio C, Bess R, et al. Current Evidence Regarding the Surgical and Nonsurgical Treatment of Pediatric Lumbar Spondylolysis: A Report from the Scoliosis Research Society Evidence-Based Medicine Committee. *Spine Deformity*, 2015; 3(1): 30-44. [2] Klein G, Mehlman C, McCarty M. (2009). Nonoperative Treatment of Spondylolysis and Grade I Spondylolisthesis in Children and Young Adults. *Journal of Pediatric Orthopaedic*. 2009; 29(2): 146-156. [3] McDonald BT, Hanna A, Lucas JA. Spondylolysis. [Updated 2019 Sep 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK513333/>

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## 1 to 30 years post-surgical HRQOL of Adolescent Idiopathic Scoliosis (AIS) with SRS-22 - a study of 1315 patients

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**Introduction:** Long-term follow-up of the quality of life with Scoliosis Research Society (SRS) -22 of adolescent idiopathic scoliosis (AIS) patients who has undergone surgical instrumentation and posterior spinal fusion has not been reported elsewhere. The hypothesis of the study was that changes of the health-related quality of life (HRQOL) could occur at different postoperative period spanning across decades. The study did not attempt to compare the results of different spinal instrumentations systems nor the type of initial curves.

**Objective:** To monitor the changes in HRQOL of AIS patients up to 30 years after surgery and notice any persistent changes over time

**Methods:** AIS patients with spinal deformities of over 45-degree Cobb angle of the major curve treated with posterior spinal fusion and different systems of posterior instrumentation in the past 30 years were invited to complete the SRS-22 through a custom-designed online system from a mobile device from November 2016 to June 2019. A total of 1315 patients had completed a total of 2445 SRS-22 questionnaires. Number of years since surgery per questionnaire were grouped per 1 to 10<sup>th</sup> year, and per 5 years afterwards. Function, pain, self-image, mental, satisfaction, and mean scores per time interval were compared.

**Results and Discussion:** Mean years since surgery was  $6.37 \pm 7.88$  years (Range: 1-31 years). Comparing with results from post-op  $\leq 1$  year, results showed function was significantly increased within first 2 years, and remained stable up to 20 years, and gradually dropped until the 30<sup>th</sup> year. Pain at operated site dropped to the lowest at 3<sup>rd</sup> year and stabilized until up to 20 years, and gradually dropped until the 30<sup>th</sup> year. Self-image was significantly increased within the first 2 years, and persistently dropped after reaching early adulthood until the 30<sup>th</sup> year. Self-image always scored persistently the lowest among all domains. Mental, satisfaction, and mean scores remained stable over the long period of the study.

**Conclusion and Significance:** This is the first long-term study comparing the quality of life of post-op AIS patients up to 30 years after surgery. Patients experienced promising quality of life 30 years after surgery, with initial fluctuation occurring mostly at early adulthood 10<sup>th</sup> and 20<sup>th</sup> years since surgery. Continuous monitoring and supports on AIS post-op patients are highly recommended particularly when they reached early adulthood. Further extended studies with HRQOL instruments into later age would help to provide better understanding of the lifelong quality of this group of patients.

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## The measurement of health-related quality of life of patients with idiopathic scoliosis – comparison of ISYQOL versus SRS-22 questionnaire

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**Introduction:** Quality of life of adolescents with idiopathic scoliosis (IS) is studied with specific questionnaires. The SRS-22 questionnaire is most commonly used however, new tools are being developed. Italian Spine Youth Quality of Life (ISYQOL), now validated into Polish, is the questionnaire developed using the Rasch analysis.

**Objectives:** The aim of the study was to compare the PLSYQOL scores versus the SRS-22 scores in order to evaluate the Polish version (PLSYQOL) of the ISYQOL for the concurrent and known-groups validity.

**Methods:** Eighty-one girls, aged  $13.5 \pm 1.8$  years, all with IS, all treated with a corrective TLSO brace, were included. Mean Cobb angle was 31.0 degree ( $\pm 10.0$ ) and mean duration of brace treatment was 2.6 years ( $\pm 1.9$ ). The patients' scores were compared as follows: (1) age: adolescents ( $<13$ ys) vs. teenagers ( $>13$ ys); (2) scoliosis severity: mild (Cobb  $10-30^\circ$ ) vs. moderate (Cobb  $>30^\circ$ ); (3) single curve pattern vs. double curve pattern. Spearman's rank correlation coefficient was used to evaluate the strength of the association between PLSYQOL and SRS-22 scores. Depending on normality and homogeneity of variance, the parametric or non-parametric comparison tests (t-test, Mann-Whitney, Welch), have been applied to assess if PLSYQOL measure and SRS22 total score were significantly different in the different groups of patients. Further investigated factors which could influence quality of life were analysed using a 2-way ANOVA performing successively the following couple of factors, respectively: (1) age and Cobb angle; (2) number of curves and Cobb angle; (3) years of treatment and Cobb angle.

**Results and Discussion:** The concurrent validity analysis showed a moderate validity of the PLSYQOL measure vs. SRS-22 (Spearman  $r=0.53$ ) with respect to the criterion of standard measure of quality of life. Using the SRS-22, no difference resulted in any of the between selected known-groups comparisons. Also, the PLSYQOL tool showed no difference between the group of adolescents vs. teenagers as well as between the group of single vs. double curves. The PLSYQOL was instead showing a significantly better quality of life in mild than moderate scoliosis. In addition, the 2-way ANOVA confirmed no interactions between severity of scoliosis and age or years of treatment or number of scoliotic curves.

**Conclusion and Significance:** The severity of scoliosis but not the age nor the curve pattern demonstrated a direct statistically significant effect on the quality of life of patients with IS when evaluated using the PLSYQOL tool; that effect could not be detected when using the SRS-22.

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